James E. Cecchi
Michael A. Innes
CARELLA, BRYNE, CECCHI, OLSTEIN,
BRODY & ANGELLO, P.C.
5 Becker Farm Road
Roseland, NJ 07068
(973) 994-1700

Attorneys for Plaintiffs
Additional Attorneys Listed Below

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ANGIE NORDSTRUM and CARLY BOWERSOCK, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. MYLAN INC., MYLAN SPECIALTY L.P., PFIZER, INC., KING PHARMACEUTICALS LLC and MERIDIAN MEDICAL TECHNOLOGIES, INC., Defendants.	Civ. Action No. **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiffs Angie Nordstrum and Carly Bowersock ("plaintiffs"), individually and on behalf of all others similarly situated, files this Complaint for Violation of the Sherman Antitrust Act and the Clayton Antitrust Act ("Complaint") against defendants Mylan Inc. ("Mylan"), Mylan Specialty L.P. ("Mylan Specialty"), Pfizer, Inc. ("Pfizer"), King Pharmaceuticals LLC ("King") and Meridian Medical Technologies, Inc. ("Meridian") (collectively, "defendants"), based upon personal knowledge as to facts pertaining to plaintiffs, and upon information and belief as to all other matters, and allege as follows:

NATURE OF THE ACTION

1. It is estimated that up to 16 million Americans are at risk of experiencing anaphylaxis – a severe, rapid-onset and potentially deadly allergic reaction most often characterized by extreme affliction of the respiratory, gastrointestinal, epidermal, heart and vasculature, and central nervous systems. Anaphylaxis occurs in response to a number of triggers, including, *inter alia*, the venom from insect stings, allergies to foods (*e.g.*, peanuts, shellfish, milk and eggs), certain food additives (*e.g.*, monosodium glutamate and artificial coloring), biological agents, manmade agents (such as latex), and medications.

2. Food allergies alone are estimated to affect 1 in every 13 children under the age of 18, with the U.S. Center for Disease Control reporting that food allergies result in over 300,000 ambulatory-care visits per year among these children. Because anaphylaxis can strike at any time and any place, the primary treatment – an intramuscular injection of epinephrine (synthetic adrenaline) to relax muscles around airways and tightening blood vessels to maintain respiratory and cardiovascular function – must be delivered quickly, on the spot, and often by non-medical personnel.

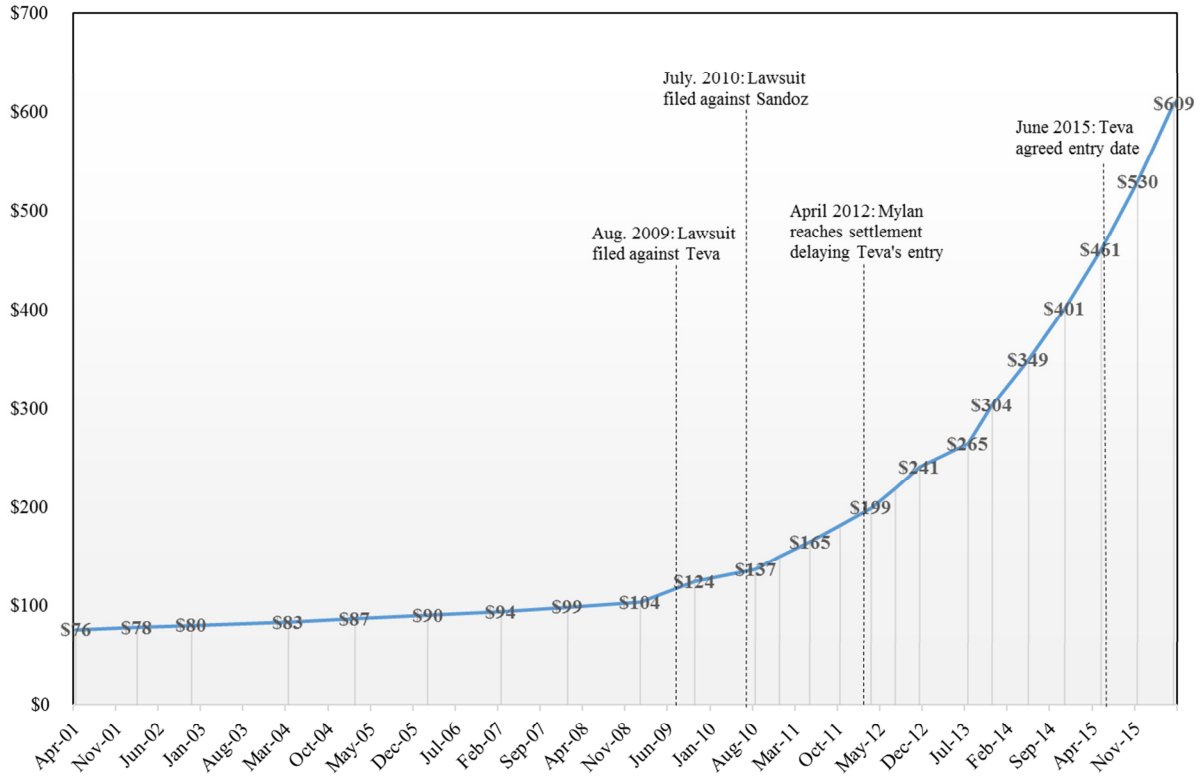
3. Collectively, defendants produce, market and sell the EpiPen, a self-injecting device that delivers epinephrine. Mylan acquired the right to market and sell the EpiPen device when it acquired Dey L.P and Merck KGaA's generics business in 2007. Defendant Pfizer, through its wholly owned subsidiaries King and Meridian, is exclusive supplier of EpiPens to Mylan. King manufacturers the epinephrine for the EpiPen, and Meridian (who holds the EpiPen auto-injector patents) manufactures the EpiPen injector device itself.

4. Since Mylan's acquisition of EpiPen, defendants have engaged in specific conduct designed to exclude rivals and harm the competitive process in the epinephrine auto-injector market. Defendants' anticompetitive and illegal exclusionary conspiracy to maintain Mylan's monopoly has made them billions of dollars at the expense of consumers and third-party payors, with EpiPen annual sales recently exceeding $1 billion, up from $200 million in revenue when Mylan first acquired EpiPen.

5. Such a massive increase in revenue has not only derived from defendants' scheming to eliminate meaningful competition, but from enormous increases in the price charged for the device (at times on multiple occasions in single years) that track Mylan's ever-strengthening market dominance.

6. Indeed, after remaining relatively stable around $75 to $100 per dosage from 2001 through the end of 2008, beginning in and around 2009, in conjunction with defendants' successful efforts to effectively curtail any meaningful epinephrine auto-injector competition then and since, Mylan has raised the price of EpiPen at a rapid pace to over $600 per dosage in 2016 – an increase from its $99 December 2007 price of more than 514%, as illustrated below:

Wholesale EpiPen Prices
2001-2016



Source: Wells Fargo Equity Research, "Mylan N.V.: MYL: Despite Recent Drop, We Remain on the Sidelines," Feb. 19, 2016, at 18.

7. There is a reason defendants have been able to maintain their epinephrine auto-injector market dominance for nearly a decade – they have illegally thwarted competition. As a specialty medical device, familiarity with how the auto-injector operates is key to getting consumers to purchase it. To compete with the EpiPen, a competitor must therefore either (a) create a generic version of the EpiPen that operates in the same way, or (b) educate parents, caretakers and guardians on how to use a new auto-injector.

8. Defendants, however, have taken steps to ensure neither avenue is open to competitors. First, by "evergreening" the EpiPen device patents (a tactic by which patent holders make minor or insignificant changes in their devices or drugs, and then reintroduce them as new products with new and extended patent life) and by aggressive misuse of legal and regulatory systems, defendants have foreclosed the market to generic competition. Second, to forestall education initiatives for novel devices, Mylan has used illegal exclusive dealing agreements to

shut competitors out of public schools, and keep new auto-injectors from schools nurses, parents, students, administrators or others that might become familiar with them. Aside from safety concerns, insurance coverage is another important factor in choosing an auto-injector, yet defendants have used their monopoly power to manipulate coverage for competitor devices as well. Beginning in 2014, Mylan began using its monopoly power to significantly raise prices on the EpiPen, then shared these monopoly rents with Pharmacy Benefit Managers ("PBMs") by systematically paying unjustifiably large discounts to PBMs in exchange for them ***excluding*** rival epinephrine auto-injectors from insurance coverage. As a result, consumers and end payers in many cases lack any meaningful choice at all for their needed epinephrine auto-injectors.

9. As a result of defendants' conduct, defendants have severely limited consumer choice and reaped massive, inflated revenues through Mylan's charging supracompetitive prices without justification. Moreover, defendants' anticompetitive activities undermine the purposes of federal and state law (including the Hatch-Waxman Act, and state and federal antitrust and fair competition laws) to increase competition and decrease pharmaceutical prices for the benefit and overall health of consumers – in this case, millions of whom are America's children.

10. Defendants' conduct has not gone unnoticed by federal regulators. According to a January 30, 2007 *Bloomberg* article entitled "Mylan Faces U.S. Antitrust Investigation on EpiPen":[1]

> Mylan NV set off a firestorm in Congress last year over skyrocketing prices of its EpiPen. Now it's facing a U.S. antitrust investigation over whether it improperly thwarted competition to the blockbuster product.
>
> * * *
>
> The FTC is looking at whether Mylan's practices violated antitrust laws, including whether small changes it made to the EpiPen effectively shielded it from competition from lower-priced products, according to a person familiar with the matter. Making minor changes to extend a patent, such as dosage levels, is known as product-hopping. Another area of scrutiny is whether Mylan entered any agreements that delayed cheaper versions of the EpiPen from coming to the market, said the person, who asked not to be named because the inquiry is confidential.

[1] David McLaughlin, Sara Forden & Jared S. Hopkins, *Mylan Faces U.S. Antitrust Investigation on EpiPen*, Bloomberg, Jan. 30, 2007, *available at* https://www.bloomberg.com /news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices.

* * *

The FTC investigation follows a backlash from Congress over prices for the EpiPen. Senator Amy Klobuchar, a Minnesota Democrat, in August called for the FTC to investigate Mylan's price hikes for EpiPen, asking the agency to look into whether the company used incentives or exclusionary contracts with insurers, distributors or pharmacies to block competing products.

Tammy Duckworth, now a Democratic Senator from Illinois, wrote to the Justice Department last year when she was in the House of Representatives to express concern about Mylan's EpiPen4Schools Program, which allows schools to receive four free auto-injectors and then buy more at a discount. That program may have suppressed competition by prohibiting schools from buying a competitor's product for a specified time period, she wrote.

The school program also drew the attention of New York Attorney General Eric Schneiderman, who said in September Mylan may have added anticompetitive terms to sales contracts with schools.

President Donald Trump attacked drug makers earlier this month, saying he'd force the industry to bid for government contracts. "They're getting away with murder," Trump said at a press conference in New York Jan. 12.

Pay-For-Delay

The FTC has aggressively pursued drug companies over agreements that delay the market entry of generic drugs to allow branded drugs to continue to enjoy their monopolies.

In a letter to Klobuchar in November, then-FTC Chairwoman Edith Ramirez declined to confirm whether the agency was investigating Mylan. She noted that the potential for the "anticompetitive product design is particularly acute in the pharmaceutical industry."

* * *

Mylan is no stranger to FTC scrutiny. In 2000, it agreed to pay $100 million to settle the agency's claims that it conspired with other companies to deny its competitors ingredients needed to make two anti-anxiety drugs so that it could raise prices for the medicines.

11. Plaintiffs have been harmed by defendants' conduct. Accordingly, plaintiffs, individually and on behalf of a Class of those similarly situated (defined herein), seek damages, injunctive relief and all other appropriate relief for defendants' wrongdoing.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 (exclusive of interest and costs), the number of the members of the Class exceeds 100, and at least one member of the putative Class is a citizen of a state different from that of one of the

defendants. This Court also has jurisdiction over this matter pursuant to §16 of the Clayton Antitrust Act ("Clayton Act"), 15 U.S.C. §26, and 28 U.S.C. §§1331 and 1337. The Court has supplemental jurisdiction over plaintiffs' pendent state law claims pursuant to 28 U.S.C. §1367.

13. Venue is appropriate within this District under 15 U.S.C. §§15(a) and 22, and 28 U.S.C. §1391(b), (c) and (d), because defendants each transact business within this District and a substantial portion of the interstate trade and commerce, hereinafter described, is carried out in this District.

PARTIES

Plaintiffs

14. Plaintiff Angie Nordstrum resides in Erie, Colorado. Ms. Nordstum's dependent has food allergies for which she has purchased several EpiPens annually from Mylan. As a result of Defendant's conduct alleged herein, Ms. Nordstrum has been forced to pay increasingly higher prices for these EpiPens. Although a portion of Ms. Nordstrum's purchases are often covered by insurance, her share of the cost has increased steadily. For example, on September 10, 2012, Ms. Nordstrum paid $227.24 for an EpiPen two pack, but on November 25, 2012, she paid $249.61 for a two pack. Then on August 17 and August 19, 2013, she paid $271.99 each for two more EpiPen two-packs.

15. Plaintiff Carly Bowersock resides in Dover, Ohio. Ms. Bowersock's dependent has food allergies for which she has purchased several EpiPens annually from Mylan. As a result of Defendant's conduct alleged herein, Ms. Bowersock has been forced to pay increasingly higher prices for these EpiPens. Although a portion of Ms. Bowersock's purchases are often covered by insurance, her share of the cost has increased steadily. For example, on October 12, 2010, when the price for an EpiPen two-pack was $135.02, Ms. Bowersock paid $54.01 for two two-packs. By November 28, 2012, the price of an EpiPen two-pack had escalated to $237.69 and her out-of-pocket cost for her two two-packs rose to $95.07. By December 26, 2015, the price for an EpiPen two-pack had ballooned to $522.09 per pack and Ms. Bowersock paid $208.84 for two two-packs.

Defendants

16. Defendant Mylan Inc. ("Mylan"), one of the largest pharmaceutical companies in the world, has its principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317. Mylan owns the trademarks on the EpiPen tradenames and has worldwide rights to market and sell EpiPens. Mylan acquired these rights in 2007 through its acquisition of Merck KGaA's generics business and Dey L.P. In 2014, Mylan executed a "corporate inversion" that moved its headquarters to the Netherlands. On information and belief, Mylan moved its headquarters out of the United States to avoid paying taxes at the U.S corporate tax rates.

17. Mylan Specialty L.P. ("Mylan Specialty") is a Delaware limited partnership with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan Specialty is a wholly owned subsidiary of Mylan Inc. Mylan Specialty is represented as a "specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drug products for the treatment of a respiratory diseases, life-threatening allergic reactions [including EpiPen and EpiPen Jr. auto-injectors], general anesthesia and psychiatric disorders." Mylan Specialty was formerly known as Dey Pharma until February 2012, when Mylan Inc. changed its name to Mylan Specialty. At all relevant times during the Class Period prior to 2013, Mylan Specialty was headquartered in Basking Ridge, New Jersey. Mylan Inc. and Mylan Specialty are collectively referred to herein as "Mylan."

18. Defendant Pfizer, Inc. ("Pfizer"), another global pharmaceutical company, has its global headquarters at 235 East 42nd Street, New York, New York 10017. Directly and through entities it owns or operates, Pfizer operates office and production facilities in New Jersey, including in Peapack, New Jersey, and Madison, New Jersey. According to its website, Pfizer employs 2,300 employees in New Jersey, including those in several of the company's "key functions, including business technology, finance, [and] legal . . . ."[2] The company has held its annual shareholder meetings in Short Hills, New Jersey, every year from, at least, 2013 through

[2] Pfizer Global Careers, About Us, http://pfizercareers.com/career-types/locations/us (last accessed April 6, 2017).

the present.[3] Through its subsidiaries King Pharmaceuticals LLC and Meridian Medical Technologies, Inc., Pfizer supplies Mylan with 100% of its EpiPens.

19. Defendant King Pharmaceuticals LLC ("King") is a wholly owned subsidiary of Pfizer. King has its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. King is in the business of developing and manufacturing medicines and technologies primarily in specialty-driven markets, including neuroscience, hospital and acute care medicines. King manufacturers and supplies the synthetic epinephrine for the EpiPen.

20. Defendant Meridian Medical Technologies, Inc. ("Meridian") is a wholly owned subsidiary of King, with its principal place of business at 6350 Stevens Forrest Road, Suite 301, Columbia, Maryland 21046. Meridian is the holder of Patent No. 7,449,012 B2 (the "'012 Patent") and Patent No. 7,794,432 B2 (the "'432 Patent") covering the EpiPen auto-injector.[4] Meridian obtained the '012 Patent on November 11, 2008 and the '432 Patent on September 14, 2010. Meridian is also the holder of approved New Drug Application ("NDA") No. 019430 covering the EpiPen. Pursuant to this NDA, Meridian manufactures the EpiPen and supplies those products to Mylan. In connection with its NDA, Meridian listed the '012 Patent and the '432 Patent in the U.S. Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book"). Meridian submitted the '012 Patent to the Orange Book on July 17, 2009 and the '432 Patent on September 15, 2010.[5]

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[3] *See* Pfizer Proxy Statement for 2013 Annual Meeting of Shareholders, https://www.pfizer.com/files/annualreport/2012/proxy/proxy2012.pdf (last accessed April 6, 2017); Pfizer Proxy Statement for 2014 Annual Meeting of Shareholders, https://www.pfizer.com/files/investors/presentations/ProxyStatement2014.pdf (last accessed April 6, 2017); Pfizer Proxy Statement for 2015 Annual Meeting of Shareholders, https://www.pfizer.com/files/investors/presentations/ProxyStatement2015.pdf (last accessed April 6, 2017); Pfizer Proxy Statement for 2016 Annual Meeting of Shareholders, http://www.pfizer.com/system/files/presentation/ProxyStatement2016.pdf (last accessed April 6, 2017); Pfizer Proxy Statement for 2017 Annual Meeting of Shareholders, http://www.pfizer.com/system/files/presentation/2017%20Proxy%20Statement.pdf (last accessed April 6, 2017).

[4] Meridian also holds the following patents that cover the EpiPen auto-injector: D543273S1 "Automatic Injector" (issued May 22, 2007); 8,048,035 B2 "Automatic Injector with Needle Cover" (issued November 1, 2011); and 8,870,827 B2 "Automatic Injector" (issued October 28, 2014).

[5] Collectively, Pfizer, King and Meridian are referred to herein as "Pfizer."

FACTUAL ALLEGATIONS

Industry Background

21. EpiPen is a disposable, prefilled automatic injection device for delivery of epinephrine (also known as adrenaline) used in the treatment of severe allergic reactions known as anaphylaxis.

22. EpiPen is used to treat signs and symptoms of an allergic emergency, some of which include hives, redness of the skin, tightness in the throat, breathing problems, and/or a decrease in blood pressure. The EpiPen has two important automatic components: needle injection and medication dispensing. It works by delivering epinephrine to reverse the effects of allergens by relaxing the muscles around airways and tightening blood vessels to maintain respiratory and cardiovascular function. "According to national food allergy guidelines, epinephrine is the ***only*** recommended first-line treatment for anaphylaxis."[6]

23. While using an epinephrine auto-injector, epinephrine is injected into the mid-anterior lateral thigh through the device's spring-loaded needle. Epinephrine auto-injectors are available by prescription only and, according to Mylan, have a limited shelf life of approximately one year.

24. Food allergy is the most common cause of anaphylaxis. According to Food Allergy Research & Education ("FARE"), these allergies affect approximately 15 million individuals in the United States.[7] Other allergens such as insect stings, medications or latex, for example, can also trigger anaphylaxis. Each year, allergic reactions account for about 200,000 emergency room visits.[8]

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[6] *See What is Epinephrine?*, Epipen.com, https://www.epipen.com/about-epipen/what-is-epinephrine (emphasis in original) (last visited Mar. 7, 2017).

[7] *See About FARE*, foodallergy.org, http://www.foodallergy.org/about (last visited Mar. 7, 2017).

[8] Selena Larson, *Outrageous EpiPen prices lead some people to make their own*, CNNMoney, Sept. 24, 2016.

25. In 2012 alone, approximately 3.1 million prescriptions were written for EpiPen in the United States, resulting in estimated sales of $671 million.[9] The epinephrine auto-injector market is now worth an estimated $1.3 billion annually with Mylan's EpiPen sales accounting for 85%.

Products and Suppliers

26. EpiPen has been sold in the United States and internationally since 1987, when it first received FDA approval. In 2007, Mylan acquired worldwide commercialization rights to EpiPen through its acquisition of Merck KGaA's generics business and Dey L.P.

27. Through its subsidiaries King and Meridian, defendant Pfizer is the exclusive supplier of the EpiPen to defendant Mylan. Prior to Mylan's acquisition, EpiPen was marketed by Dey as part of an agreement with Meridian.

28. In 2003, the first alternative to EpiPen was introduced under the name Twinject, which was eventually renamed Adrenaclick. For the past 13 years, various companies have produced Adrenaclick, with Impax acquiring the rights in March 2015. Impax currently produces both Adrenaclick and a generic version.[10] Adrenaclick's market share has ranged from only 2% in 2013 to 8% in 2016.[11]

29. In 2008, Teva Pharmaceuticals ("Teva") attempted to enter the market with a generic epinephrine auto-injector through the Abbreviated New Drug Application ("ANDA") process.[12] After receiving notice of Teva's ANDA on July 20, 2009, to protect their EpiPen

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[9] Leerink Swann Healthcare Equity Research, "Mylan, Inc.: EpiPen Survey Confirms Auvi-Q Threat; We Believe Shares Reflect Competition," Apr. 9, 2013, at 18.

[10] In May 2010, a generic epinephrine auto-injector was released for distribution. This epinephrine auto-injector has no trade name currently and is distributed by Greenstone, a generic division of Pfizer. It has been authorized by Shionogi, the maker of Adrenaclick, as a generic of Adrenaclick.

[11] Sam Wood, *A cheaper way to get epinephrine pen, if you know how*, Philly.com, Aug. 31, 2016. *See also* Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 Cornell L. Rev. Online 53, 57-58 (2017) (hereafter "Carrier & Minniti").

[12] The Hatch-Waxman Act allows generic firms to avoid the expensive and lengthy NDA by filing an ANDA. By demonstrating that its drug possesses the same active ingredient, route of administration, bioequivalence (rate and extent of drug absorption), and other characteristics of

monopoly, defendants conspired to have Meridian and King file suit against Teva for alleged patent infringement. In April 2012, the parties reached a settlement whereby Teva agreed to delay entering the market until June 22, 2015.[13] On information and belief, Teva received unjustifiable consideration, incentives and benefits from King in exchange for the agreed-to market entry delay. Indeed, no rational economic actor with a viable product would refrain from entering a lucrative "blockbuster" market unless they received some form of valuable consideration. As described in more detail below, EpiPen prices more than doubled during the period in which Teva did not enter the market. This settlement has come under congressional scrutiny as an illegal "pay for delay" agreement.[14]

30. The Teva settlement was also intended to foreclose all other auto-injector generic competition for the same time period as well. Defendants knew that an agreed-to delay with Teva would be subject to the Hatch-Waxman Act's 180-day exclusivity award, which grants 180 days exclusivity to the first generic to challenge a brand firm's patent, claiming it is invalid or not infringed. The exclusivity period does not begin until the first-filing generic enters the market. In the case of Teva – as the first filer – that would be a minimum of three years in the future. Thus, as a result of Teva's delayed market entry, defendants delayed all generics seeking ANDA applications based on the EpiPen.

31. In 2010, Sandoz, Inc. ("Sandoz") made a similar attempt to enter the market through a generic alternative to EpiPen. As with Teva, defendants conspired to have King file a patent infringement suit against Sandoz in response to its ANDA filing. According to a 2016 U.S. Securities and Exchange Commission ("SEC") Form 10-Q filed by Pfizer, Sandoz's ANDA

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the brand, the ANDA process allows firms to rely on the brand's safety and effectiveness studies and avoid the need to undertake independent clinical studies.

[13] *Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement with Teva*, PR Newswire, Apr. 26, 2012.

[14] *See* Ben Seal, *U.S. Senator Prods Mylan on EpiPen 'Pay for Delay' Concerns*, Nat'l L.J., Sept. 28, 2016, *available at* http://www.nationallawjournal.com/id=1202768792860/US-Senator-Prods-Mylan-on-EpiPen-Pay-for-Delay-Concerns?slreturn=20170114165452.

is ongoing[15] and the litigation is stalled with the court entering an order staying the FDA process and administratively terminating the action, to be reopened upon letter request by any of the parties.[16] No party has reopened the case.

32. Between January 2013 and October 2015, Auvi-Q (initially introduced as "e-cue") also tried to compete with the EpiPen. This device differed in size, shape and operation, using a recorded voice to provide instruction to users. Rather than pursuing entry through an ANDA, Intelliject filed a new drug application under §505(b)(2) – in other words, a "paper NDA."[17]

33. Once again, defendants acted quickly to protect their monopoly. Through defendant King, yet another patent infringement lawsuit was filed in January 2011 to block Intelliject's NDA. After tying Intelliject up in litigation for over a year, that lawsuit was eventually settled in February 2012. As part of a settlement however, Intelliject agreed to postpone the introduction of Auvi-Q/e-cue for even longer – until November 15, 2012. Thus, defendants blocked this potential competitor for almost two years.

34. By early 2015, defendants had effectively targeted and tied up potential rivals through King's tactical sham litigation. But as Teva's market entry loomed, defendants needed another member of their team to create more delay. Delay has been an immensely valuable core of defendants' scheme. Indeed, "[f]or a billion-dollar drug product like the EpiPen, each day of delay mean[s] an extra $3 million."[18] Thus, in January 2015, Mylan made another play to forestall Teva's entry by filing a "citizen petition" with the FDA. A citizen petition is intended for members of the public to raise safety concerns with the FDA but, in this case, was being used

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[15] Pfizer SEC Form 10-Q for the quarterly period ended July 3, 2016, filed August 11, 2016, at 33.

[16] *King Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 10-cv-3568 (D.N.J. May 10, 2011), Dkt. No. 66.

[17] Carrier & Minniti, 102 Cornell L. Rev. Online at 63. A "paper NDA" differs from an ANDA in a number of ways, one of which is that approval for a paper NDA product relies in part on a previously approved product's safety and efficacy data. Yet the products are different in some way.

[18] Carrier & Minniti, 102 Cornell L. Rev. Online at 66.

by defendants as an anticompetitive means of continuing to block Teva from competing with them for auto-injector sales. Such petitions by brand drug manufacturers "are almost always (92%) denied" but typically have the effect, absent some intervening event, of impeding market entry efforts of a generic for about 150 days, while the FDA considers the petition.[19]

35. In May 2015, however – four months after the petition's filing and mere weeks before an expected FDA response within that 150-day time period – Mylan (as planned with its co-conspirator co-defendants) strategically filed a questionable supplemental study, asserting that Teva's device could not be operated without patient retraining. As discussed in the *Cornell Law Review Online*, though:

> Experts have explained . . . that Mylan's supplemental study "had a lot of problems" as it "lacked a control group; did not study the actual generic but a prototype instead; used a small number of participants; failed to provide them with proper instructions for use; and told participants to watch a video rather than actually use the Teva device."
>
> Shedding even more light on the questionable petition and supplemental study is its timing. In a development of which the industry would be keenly aware, Teva filed its ANDA against the Epi-Pen in 2008. And court documents show that Teva produced its ANDA filing in the course of litigation on September 17, 2010. This material included "detailed product descriptions, drawings, and instructions for use" for Teva's proposed generic.
>
> At the time (and to this day), Mylan was working hand-in-hand with Meridian/King, with the former taking over Orange Book sponsorship of the drug application and the latter targeting rivals in litigation.
>
> * * *
>
> We think it reasonable to conclude that Mylan's (1) filing of a petition years after invariably knowing about Teva's generic, (2) filing of a petition calculated to delay entry after settlement, and (3) late-filing of a supplemental study together comprised a strategy to delay Teva's ANDA approval ***beyond*** the ***already-delayed*** agreed entry date of July 22, 2015.[20]

36. While Teva's application was ultimately denied by the FDA in February 2016, defendants could not have known that at the time they executed their plan to block Teva. Moreover, their plan did not just block Teva, but all competition from anyone entering the generic epinephrine auto-injector market.

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[19] *Id*. at 64.

[20] *Id*. at 64-66 (footnotes omitted; emphasis in original).

Pricing

37. The price of EpiPen over time dramatically illustrates the cost of defendants' conspiracy.

38. As shown in the figure below, list prices for EpiPen were relatively stable from 2001 to 2007, increasing slightly from $76 in April 2001 to $99 in December 2007. A notable price increase occurred in 2009 when Mylan introduced the "second generation" EpiPen. In connection with that "new" product launch, Meridian obtained new patents on the device that are not set to expire until 2025. After extending the patent life of the EpiPen, Mylan increased prices by 20% from $103.50 in January to $124.30 in October.[21]

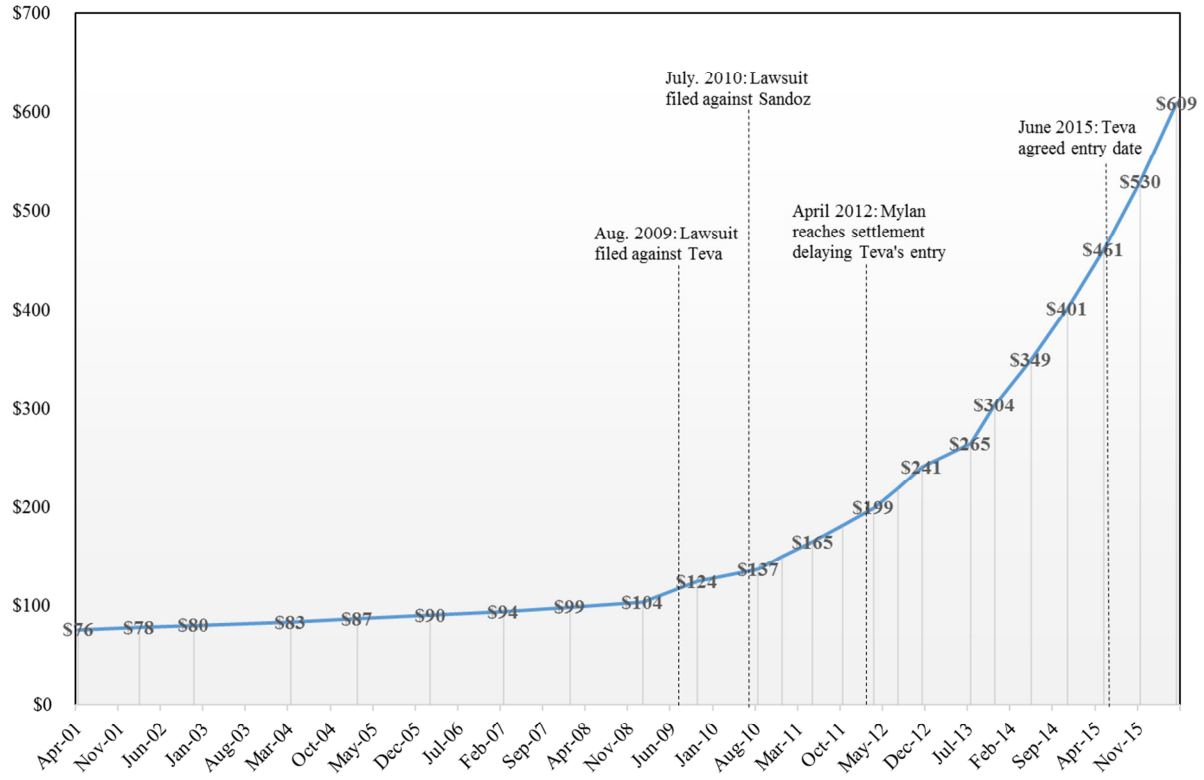
39. Since Mylan's acquisition in 2007, prices have increased from $93.88 to $608.61 in 2016, an increase of more than 548%.[22] As noted in a 2016 analyst report, the magnitude of price increases have also grown over time: "[O]ver the past 13 years, the package price for EpiPen increased at a CAGR of 16%, but over the past 10 years it increased 20% annually, while over the past 5 and 3 years, respectively, the annualized increases were approximately 30%."[23]

[21] According to Mylan's 2009 Form 10-K, "on October 1, 2009, Dey launched a new design of the epinephrine auto-injector in the U.S., which provides enhanced user-friendly attributes to the pen." *See* Mylan SEC Form 10-K for the fiscal year ended December 31, 2009, filed February 26, 2010, at 7. *See also* Morgan Stanley Research, "Mylan, Inc.: Upgrade to Overweight on Compelling Risk-Reward," Nov. 30, 2011, at 19 (stating "[n]ext generation EpiPen Auto-Injector launched in 3Q (note significant price increase in October for second generation device)").

[22] Jonathan D. Rockoff, *Mylan Faces Scrutiny Over EpiPen Price Increases; Criticisms mount after drugmaker raises cost of allergy treatment by 548% since 2007*, Wall St. J., Aug. 24, 2016.

[23] Wells Fargo Equity Research, "Mylan N.V.: MYL: Despite Recent Drop, We Remain on the Sidelines," Feb. 19, 2016, at 17.

Figure 1: Wholesale EpiPen Prices
2001-2016



Source: Wells Fargo Equity Research, "Mylan N.V.: MYL: Despite Recent Drop, We Remain on the Sidelines," Feb. 19, 2016, at 18.

40. According to one report, the benefits of EpiPen price increases have accrued largely to defendants, rather than to other members of the supply chain (*i.e.*, pharmacies, PBMs and distributors): "We believe that Mylan has been raising list price consistently for years, and we believe that Mylan has realized most of that benefit – not the PBMs [(pharmacies)] and not the distributors."[24] Using data published by IMS Health (shown in Table 1 below), the same report estimates that the weighted average cost ("WAC") of EpiPen "has increased by ~30% per year from 2011 through 2015" and has been realizing growth in net prices of 23%.[25]

[24] Leerink Partners Equity Research, "Pharmacy Benefit Managers: PBMs Use Competing Products to Reduce Costs – EpiPen's Price is Mylan's Issue," Aug. 26, 2016, at 2.

[25] *Id.* at 3.

Table 1: IMS EpiPen Sales

Year	IMS Sales ($ Millions)	IMS Units (000's)	IMS WAC	IMS Sales % Change	IMS Units % Change	IMS WAC % Change
2011	$393	3,173	$132			
2012	$650	3,310	$201	65%	4%	52%
2013	$837	3,416	$254	29%	3%	26%
2014	$1,201	3,656	$337	43%	7%	33%
2015	$1,691	3,930	$445	41%	7%	32%

41. Research indicates that the high EpiPen prices exhibited after 2009 cannot be explained by production costs. In an *NBC News* article, Kevin Deane, head of medical technologies for PA Consulting Group, estimated that the cost of producing EpiPen could be no more than $30.[26]

42. As stated in one report, "EpiPen has been a growth driver for [Mylan] over the past three years, driven by price increases and expanded treatment rates."[27] A November 2011 analyst report estimated that EpiPen price increases in excess of 21% resulted in an increase in margins from 29% in 2010 to 43% in 2011. Margins were expected to continue trending higher due to additional price increases, including a 9.9% increase on October 18, 2011 and Mylan's decision on August 24, 2011 to discontinue selling single packs and exclusively market double packs.[28]

43. Similarly, in March 2012, one analyst report noted that Mylan's projected growth in specialty segment sales was "driven mainly by EpiPen . . . , which despite being a mature

[26] Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than $30*, NBC News, Sept. 6, 2012 ("[T]he base components for each EpiPen, including the plastic cap, tube, and needle, might cost between $2 to $4 to purchase. Pharmacists contacted by NBC estimate that the epinephrine inside costs less than $1. Additionally, based on industry norms, Mylan would have to pay a licensing fee to companies involved in research and development of the device. This amount might generally multiply the price that Mylan pays Pfizer's wholly owned subsidiary Meridian Medical Technologies, which manufactures the epinephrine autoinjector between two and five times . . . ."), *available at* http://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091.

[27] Leerink Swann Healthcare Equity Research, "Mylan, Inc.: EpiPen Survey Confirms Auvi-Q Threat; We Believe Shares Reflect Competition," Apr. 9, 2013, at 4.

[28] Morgan Stanley Research, "Mylan, Inc.: Upgrade to Overweight on Compelling Risk-Reward," Nov. 30, 2011, at 3.

product has continued to generate very strong revenue growth with the help of price increases ([Mylan] just took one for 9.9% a week ago and sees room for even further increases of perhaps 5-10% annually, if not higher), shifting to a two-pack from a single-pack, and limited competition given strong barriers to entry."[29]

44. According to researcher ABR|Healthco, EpiPen "clobbers its rivals and provides about 40 percent of Mylan's operating profit." The firm estimated that EpiPen margins increased from 9% in 2008 to 55% in 2014.[30]

Comparison to Prices and Markets for Epinephrine Injectors in Europe

45. Compared to the United States, the cost for a set of two EpiPens in Europe ranges from only about $100 in France and the United Kingdom to just over $200 in Germany.

46. While Europe's significantly lower prices are, in part, the result of legislation restricting price increases on branded drugs, a portion of the lower prices can be attributed to pricing discipline imposed by competition from two alternative products that are not offered for sale in the United States.

47. In the United Kingdom, non-contractual price agreements between the Department of Health and the Association of the British Pharmaceutical Industry ("ABPI") are established under the Pharmaceutical Price Regulation Scheme ("PPRS") for all branded medicines available from the National Health Service ("NHS"). "The purpose of the scheme is to achieve a balance between reasonable prices for the NHS and a fair return for the pharmaceutical industry."[31] In February 2009, the PPRS reduced prices by an estimated 3.9%.

48. There are also, however, two alternative products currently available in the United Kingdom that have prevented Mylan from achieving the same dominant market share it has in the United States.

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[29] Susquehanna Financial Group, "Mylan, Inc.: A Good Growth Story that Should Have Legs," Mar. 14, 2012, at 6.

[30] Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, Bloomberg Businessweek, Sept. 23, 2015.

[31] Anaphylaxis Campaign, *Statement – EpiPen pricing situation in the US – 26th August 2016*, Anaphylaxis.org.uk, Aug. 26, 2016, *available at* http://www.anaphylaxis.org.uk/2016/08/26/statement-epipen-pricing-situation-us-26th-august-2016/.

49. Jext, sold by Alk-Abello and approved for sale in Europe in 2011, has gained an estimated 11% of the European market for epinephrine auto-injectors. A set of two Jext pens costs the NHS about 48 pounds, ***down about 17% since 2013***.

50. According to a 2012 report, the cost per dose for Jext was initially higher than the cost of EpiPen, in part due to Jext's longer shelf life.

Costs per dose (£)	EpiPen	Jext
0.15 mg	26.45	28.77
0.3 mg	26.45	28.77

51. The other alternative to EpiPen, Emerade, was introduced in 2014 and has an estimated 20% of the market in the United Kingdom and Sweden and 6% of the market in Germany.[32]

52. As a result of this competition in Europe, EpiPens and other epinephrine injectors are considerably more affordable there.

Relevant Antitrust Product Market

53. The relevant antitrust product market is the market for epinephrine auto-injectors, including EpiPen and any AB-rated EpiPen generics.

54. There are no adequate substitutes for epinephrine auto-injectors. EpiPen is priced at a premium compared to other epinephrine auto-injectors and, as a result of defendants' conspiracy, prices of competing products have not been able to discipline EpiPen's prices.

55. Despite the high margins earned on EpiPen sales, few substitutes have emerged in the epinephrine auto-injector market. Those competitors that have managed to enter the market have been met with limited success. According to a Barclays Capital analyst report, "EpiPen has faced competitors previously, although none have gained competitive traction."[33]

[32] A third alternative, Anapen, was introduced in 2011. That product was sold in the United Kingdom, but is no longer available.

[33] Barclays Capital Equity Research, "Mylan Inc.: Overcoming EpiPen's Wall of Worry," Mar. 7, 2012, at 1.

Relevant Antitrust Geographic Market

56. The relevant geographic market for the sale of epinephrine auto-injectors is the United States. Mylan's 2010 Form 10-K confirms that the "principal market" for the company's specialty segment, which includes EpiPen sales, is "pharmaceutical wholesalers and distributors, pharmacies and healthcare institutions primarily in the U.S."[34]

Defendants' Exploitation of Mylan's Monopoly Power

57. "Monopoly power is conventionally demonstrated by showing that both (1) the firm has . . . a high share of a relevant market and (2) there are entry barriers – perhaps ones created by the firm's conduct itself – that permit the firm to exercise substantial market power for an appreciable period."[35]

58. Since at least 2009, Mylan has had monopoly power in the market for epinephrine auto-injectors in the United States.

Market Share

59. As shown in Table 2 below, EpiPen maintained a 94% share of the epinephrine auto-injector market from 2009 to 2012, decreasing slightly from 2009 to 2010 and increasing to nearly 100% in 2012. According to one report, "[a]s EpiPen has been able to maintain its share despite Twinject competition, we would not be surprised to see ongoing price increases for the franchise."[36]

[34] Mylan SEC Form 10-K for the fiscal year ended December 31, 2010, filed February 24, 2011, at 80.

[35] U.S. Department of Justice, *Competition and Monopoly: Single-firm Conduct Under Section 2 of the Sherman Act* 21 (2008), *available at* www.usdoj.gov/atr/public/reports/236681.htm.

[36] J.P. Morgan North American Equity Research, "Mylan Inc.: A Closer Look at Dey," Apr. 1, 2009, at 4.

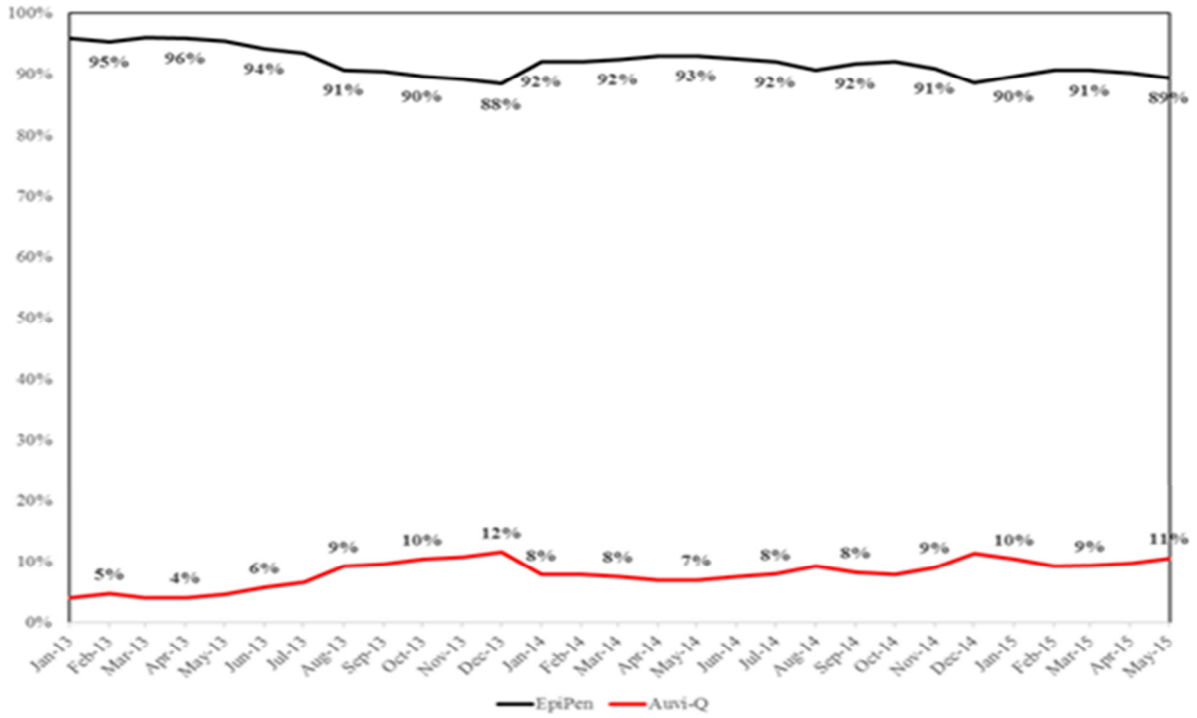
Table 2: Epinephrine Auto-Injector Market Shares, 2009-2012

Product/Trademark	2009	2010	2011	2012
EpiPen	95.70%	94.70%	94.10%	99.50%
Andrenaclick/Twinject	1.00%	3.40%	5.10%	0.20%
Generic Epinephrine	3.20%	1.90%	0.70%	0.20%

Source: Leerink Swann Healthcare Equity Research, "Mylan, Inc.: EpiPen Survey Confirms Auvi-Q Threat; We Believe Shares Reflect Competition," Apr. 9, 2013, at 18.

60. EpiPen's market share began to fall slightly in 2013 with the introduction of Auvi-Q, as shown in Figure 2 below. After dropping to 88% in December 2013, EpiPen's market share reversed its downward trend, increasing to 93% in May 2014.

Figure 2



61. In October 2015, Auvi-Q left the market, leading to a "substantial increase in EpiPen volume growth."[37]

62. EpiPen has dominated the market for epinephrine auto-injectors since 2009.

[37] BTIG Equity Research, "Mylan N.V.: Epipen Market Shares Surge Post Auvi-Q Recall; Buy," Nov. 30, 2015, at 1.

Barriers to Entry

63. There are a number of barriers to entry into the market for epinephrine auto-injectors. These entry barriers, combined with EpiPen's high market share, support the economic inference that Mylan holds monopoly power in the relevant antitrust market.

Patents

64. According to the 2016 Orange Book, an annual compilation of brand name drugs and their associated patents, defendants currently own four patents related to epinephrine auto-injectors, all of which are set to expire in November 2025. Defendants' control over these patents means that firms seeking entry with a generic injector product prior to 2025 can only do so by certifying that each patent is invalid or will not be infringed by a generic device.

65. Given their collective scheme, to quote a 2012 analyst report, defendants "ha[ve] been taking steps on multiple fronts to stymie generics, including the introduction of a redesigned autoinjector in 2009 that offers some incremental safety features and carries additional IP protection."[38] Specifically, in a 2009 earnings call, Mylan's Chief Executive Officer ("CEO") Heather Bresch ("Bresch") "told investors that the company would be introducing a new version of EpiPen's auto-injector device, one with patent protection that would make it more difficult for a generic competitor to enter. The month that the company launched the improved product, Mylan boosted the list price of the drug by 20 percent." According to Jacob Sherkow, an associate professor at New York Law School, by revising its product, Mylan was "'essentially wiping the slate clean – if any generic company wants to create a generic version, they're going to have to start a lawsuit.'"[39]

Development of an FDA-Approved Delivery Device

66. Although epinephrine is a generic drug, the delivery device has proven to be a significant barrier to entry.

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[38] *See* Susquehanna Financial Group, "Mylan, Inc.: A Good Growth Story that Should Have Legs," Mar. 14, 2012, at 12.

[39] Carolyn Y. Johnson & Catherine Ho, *How Mylan, the maker of EpiPen, became a virtual monopoly*, Washington Post, Aug. 26, 2016.

67. In describing the increases in EpiPen prices, a 2016 article stated that "[c]ompetition could drop the price of EpiPens, but there are hurdles to entering the marketplace. A device can never fail . . . . Therefore, they go through exhaustive, continuous testing that constitutes a significant capital investment for a drugmaker."[40]

68. As explained by one commentator:

> Epinephrine is extremely cheap – just a few cents per dose. The complications come from producing the easy auto-injecting devices. Mylan "owns" their auto-injector device design, so competitors must find work-arounds in their devices to deliver the epinephrine into the patient's body. This task, coupled with the tangled mess of FDA red tape, has proven to be difficult for would-be EpiPen competitors. It's like expecting somebody to come up with a new way to play baseball without bases, balls, gloves, or bats, but still getting the game approved by the MLB as a baseball game substitute.[41]

69. Until the EpiPen delivery device patents expire, or are successfully challenged, the capital investment in developing a new and dependable delivery device is an expensive hurdle to leap.

Regulation

70. In addition to patents, federal and state regulations governing epinephrine auto-injector sales have created additional barriers to entry. One report noted that it did not "expect a generic version of EpiPen for the next several years" and that even if Teva were to have succeeded in patent litigation, "both regulatory hurdles and patient preference based on the strength of the brand for EpiPen will provide protection to the franchise."[42] Another report stated that FDA approval would likely be the "largest obstacle facing Teva and other generic companies in their attempts to market a generic version of EpiPen."[43]

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[40] Adam Rubenfire, *Lack of competition leads to EpiPen pricing woes*, Modern Healthcare, Mar. 28, 2016, *available at* http://www.modernhealthcare.com/article/20160328/NEWS/160329971.

[41] Jonathan Newman, *The Lack of EpiPen Competitors is the FDA's Fault*, Mises Wire, Aug. 24, 2016, *available at* https://mises.org/blog/lack-epipen-competitors-fdas-fault.

[42] Barclays Capital Equity Research, "Mylan Inc.: Overcoming EpiPen's Wall of Worry," Mar. 7, 2012, at 3.

[43] UBS Investment Research, "Mylan Inc.: Don't Underestimate EpiPen," July 30, 2012, at 5.

71. In November 2013, after extensive lobbying efforts by defendants, President Obama signed the School Access to Emergency Epinephrine Act, which "gave funding preferences for asthma treatment grants to states that maintained an emergency supply of EpiPens."[44] As the "near sole supplier of the devices" due to defendants' conspiracy and actions taken to maintain the EpiPen monopoly, passage of this law meant that "Mylan [and the other defendants] stood to make even more money."[45] In 2010, only eight states had epinephrine legislation in schools. By 2016, 48 states had enacted policies or laws allowing or requiring schools to stock epinephrine auto-injectors.[46]

72. By utilizing Mylan's EpiPen's market power, defendants, through Mylan, further required schools to enter into exclusive dealing agreements with Mylan in exchange for supply of EpiPens, as explained in more detail below. Thus, defendants have manipulated these regulations to erect further barriers to entry.

Familiarity with a Potentially Life-Saving Medical Device

73. As a potentially lifesaving medical device, familiarity with the product is critical to its sales. Parents of children with food or insect allergies want peace of mind that not only will they know how to use the auto-injector in the event of an emergency, but that any other caretaker or bystander on hand will know how to use it as well.

74. For instance, in describing Teva's expected entry into the epinephrine auto-injector generics market in 2015, one report stated that it did not expect the product's introduction to result in a "typical oral-generic-like generic switch."[47] This is because "EpiPen has unique circumstances: a life-saving device, often for kids, with extremely strong brand-

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[44] Aaron E. Carroll, *The EpiPen, a Case Study in Health System Dysfunction*, N.Y. Times, Aug. 23, 2016. Although this article states the law required schools to maintain an emergency supply of "EpiPens", the law actually requires only an emergency supply of epinephrine and does not specify any particular epinephrine product.

[45] *Id.*

[46] EpiPen4Schools Infographics, *available at* https://www.mylan.com/-/media/mylancom/files/news/epipen4schools%20infographics.pdf (last visited Mar. 7, 2017).

[47] Jeffries Equity Research, "Antares Pharma, Inc. (ATRS): Initiating at Buy; Self-Injecting Profitable Growth," Dec. 19, 2012, at 23.

recognition and patient familiarity. . . . [M]any patients would be very uncomfortable with a 'generic' or different looking/named device."[48]

75. Requirements for patient training have also discouraged substitution in some instances. During a 2009 earnings call, Mylan's CEO explained the importance of training:

> Given the fact that how important training is of the product and the importance and the enhancements that have been made, we certainly believe that if there were ever to be a generic on the market it would have to match the product that we have. But like I said, we see that as unlikely.[49]

Defendants' Illegal Acquisition and Maintenance of Mylan's Monopoly

76. Firms that have monopoly power are able to exclude rivals and harm the competitive process.[50] Where a firm has monopoly power, buyers are not able to switch away from its products because the loss of supply is too great. This gives the firm with monopoly power the ability to impose exclusionary conditions on its buyers that can adversely affect rivals.

77. Mylan, with the assistance and support of its co-conspirator co-defendants, possesses and exercises the power to exclude rivals and has illegally acquired and maintained its monopoly power. Defendants have done this in several ways, including by (a) paying PBMs to shut out competition, (b) coercing schools to enter into exclusive dealing contracts, and (c) manipulating patent infringement litigation to forestall entry of generic and novel competitors, among other anticompetitive means.

Mylan Abuses the EpiPen Monopoly by Paying PBMs to Exclude Competition

78. A monopolist is defined by its ability to raise prices without sacrificing sales volume. That is the very essence of market power.

79. As explained in more detail below, defendants used this power to raise prices which then afforded them larger margins on the sale of each EpiPen. Mylan used these larger margins to offer to certain Pharmacy Benefit Managers (PBMs) to exclude competitors from their Preferred Drug Lists – rebates other manufacturers could not afford to match because they

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[48] *Id.*

[49] Mylan Q3 2009 Earnings Conference Call, Oct. 29, 2009.

[50] *See* Robert Pindyck & Daniel Rubinfeld, *Microeconomics* 366-68 (7th ed. 2009).

lacked the market power to increase prices without sacrificing sales volume. In this way, defendants abused their monopoly power to harm competition.

80. PBMs are third-party administrators of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans.

81. According to the American Pharmacists Association ("APhA"):

> PBMs are primarily responsible for developing and maintaining the formulary, contracting with pharmacies, negotiating discounts and rebates with drug manufacturers, and processing and paying prescription drug claims. For the most part, they work with self-insured companies and government programs striving to maintain or reduce the pharmacy expenditures of the plan while concurrently trying to improve health care outcomes.[51]

82. Prescription drug insurance plans only cover costs for drugs that appear on their PBMs' formulary, or list of covered drugs. They do not cover any of the costs for drugs that do not appear on their formularies.

83. Express Scripts and CVS Caremark are the two largest PBMs in the United States. In 2014, they combined to cover well over 50% of the PBM market in the United States.

84. In 2013, CVS Caremark became the first PBM to issue a list of ***excluded*** drugs that would not be covered by insurance plans for which it provided services. In 2014, Express Scripts followed suit and issued its own Preferred Drug List ***Exclusions***.

85. The PBMs did this, in part, as a negotiation tool to leverage greater discounts and rebates for drugs that are ***not*** excluded from its formulary. Defendants, however, saw this as an opportunity to exclude rivals.

86. Defendants took advantage of Mylan's monopoly power and in response to this perceived opportunity, Mylan hiked prices by 15% in July 2013. It then tacked on four more successive 15% increases in February 2014, September 2014, April 2015 and November 2015, taking the price from $304 all the way up to $530 in the course of less than 30 months.

87. By doing this, Mylan created additional profit margin from which it could pay a portion of these monopoly profits to PBMs in the form of significantly higher rebates and

[51] *Pharmacy Benefit Management*, https://www.pharmacist.com/sites/default/files/files/Profile_24_PBM_SDS_FINAL_090707.pdf.

percentage discounts. For example, in her congressional testimony, Mylan's CEO offered a chart that showed while the Wholesale Acquisition Cost for EpiPen two-packs rose from $401 in September 2014 to $530 in November 2015, Mylan's profit per two-pack actually ***dropped*** from $235 to $219 respectively. On information and belief, this temporary drop in profit margin was due to larger rebates paid to PBMs.

88. As they knew at the time, defendants' largest competitors, Auvi-Q and Adrenaclick, could not raise prices to inflate their margins, and thus could not offer PBMs similarly inflated rebates or discounts on their products.

89. On information and belief, in exchange for defendants' increased rebates and discounts, Express Scripts added Auvi-Q to its 2014 Preferred Drug List ***Exclusions***, and CVS Caremark added Adrenaclick to its 2014 list of Formulary Drug ***Removals*** – thus effectively removing these EpiPen alternatives from consumer and end payor choice.

90. These exclusions had an immediate impact on EpiPen's market share. For example, while Auvi-Q had steadily been gaining market share up to 12% in 2013, being added to the exclusion list immediately cut its share to 8% in 2014. Others observing the market recognized what defendants had done. As reported in an *NBC News* article dated September 6, 2016, citing pharmaceutical industry analyst and advisor Adam Fein:

> Pharmaceutical companies will sometimes pay PBMs steeper discounts in order to shut out their competition, said Fein. And, in the past, two of the biggest PBM companies have excluded EpiPen competitors from coverage: In 2014, Express Scripts excluded AuviQ, and in 2015 Caremark didn't cover Adrenaclick. This meant that if your insurance company was their customer, you would not be able to get the EpiPen alternative without paying full retail price.[52]

91. That article went on to quote Express Scripts spokesman Brian Henry, who acknowledged that "'[i]n 2014 and 2015, we [Express Scripts] leveraged the competition between EpiPen and Auvi-Q to earn additional discounts for our clients.'"[53]

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[52] Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than $30*, NBC News, Sept. 6, 2016, *available at* http://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091.

[53] *Id.*

92. Mylan has also acknowledged that it leverages its rebate deals and formulary position to protect and enhance its market share. In a Q3 2013 analyst call, Mylan CEO Bresch stated:

> As far as EPIPEN goes, we had a phenomenal quarter. I couldn't be happier with the results that EPIPEN continues to produce, and the return on our investment of education and awareness and direct-to-consumer advertising has very much paid off. And as I said, we see a lot of runway room left.
>
> There's still a fairly small number of at risk patients for anaphylaxis carrying an EPIPEN, and we believe that our message is being heard. And as far as the competition landscape goes, as we've said all along, that shared voice in a market like this that shows this much reaction to education and awareness is beneficial, obviously, for the patient, and we believe we'll continue to get our very much disproportionate share around this marketplace for years to come.
>
> ***I think as far as pricing, our formulary position, we are in a number one formulary position with all the major formularies and don't see any of that changing next year***.[54]

93. Likewise, in a Q2 2014 analyst conference call, the following exchange occurred:

> **Elliot Wilbur – Needham & Company, LLC, Research Division**
>
> First question is for Heather with regard to the EpiPen franchise. Obviously seeing a lot of noise in the market and a lot of shifting regarding formulary positioning ***and I guess despite the fact that EpiPen is a dominant product in the category and sort of the price leader, it's still maintained very strong formulary positioning***.
>
> And I'm just curious sort of what the trend has been in rebating on the product? Whether that strong formulary position has come increasingly at the cost of higher rebates?
>
> And maybe you could just sort of talk about kind of ability to grow the product sort of in excess of the Rx volume growth trends that we're currently seeing in the marketplace. And then just as a second question here and just to confirm, Heather, delays in expected product approval activities are purely a function of FDA timelines and don't have anything to do with recent inspection observations at any of your facilities.
>
> **Mylan CEO Heather Bresch**
>
> Okay. Sure. So what I'd say, Elliot, around EpiPen obviously when you've got a multiple epinephrine product marketplace, it leads to a more competitive positioning, both with the pharmacies, as well as payers. ***I think that given the breadth and scope of our business, that we've been able to manage and to obviously remain very competitive in that structure***.
>
> ***But with that being said, we're going to do whatever we need to do to really maintain that market leadership, and like I said, and continue to look at***

[54] Mylan Q3 2013 Earnings Conference Call, Oct. 31, 2013.

> ***ways that we can enhance and add to this franchise***. So I think the strong script trends are just indicative of how much runway room is still out there.
>
> Because I think as we continue to educate, like I said, not only customers, but truly everything from schools to establishments on how important to have access to EpiPen is, we've just continued to see those campaigns very much take hold and very much continue to drive these script trends throughout the United States. So I think, like I said, it's just indicative of how much runway is left and the return on our capital being very high based on the demand that it's creating in the marketplace.[55]

94. Again in a Q2 2015 analyst call, Bresch stated:

> We're already in a multi-epinephrine market, to your point. We're competing – we're very proactively competing for market share with our payers and formularies and we'll continue to do so.[56]

95. And again in a Q4 2015 analyst call, Bresch stated:

> [T]hroughout 2015, especially at the beginning of the year . . . Mylan had been very proactive, in maintaining our market share in a very competitive multi-epinephrine marketplace. And that involved entering contracts with our payers, long-term multi-year contracts.
>
> * * *
>
> I think what we did say, is that we were very proactive. And I had very – I think very straightforward conversations with all of the investors and shareholders, that ***we were maintaining market share. And to do so, that required aggressive rebating***, and that's why that we absorbed much of that during 2015.
>
> * * *
>
> As far as the contracts that I mentioned, look we were – as I mentioned in 2015, the aggressiveness came from the current multi-epinephrine market and the players that were in there, including Auvi-Q and Sanofi.[57]

96. Although Bresch routinely peppers her public statements with reference to a "very competitive" marketplace, as described above the marketplace is in fact dominated by EpiPen. Mylan's "aggressive" positioning of EpiPen within the dominant formularies is facilitated only by the company's monopoly power which allows it to charge consumers ***higher*** prices for its product which it then shares with PBMs (which create the formularies) through substantially enhanced rebates in exchange for ***excluding*** insurance coverage for rival products. The net

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[55] Mylan Q2 2014 Earnings Conference Call, Aug. 7, 2014.

[56] Mylan Q2 2015 Earnings Conference Call, Aug. 6, 2015.

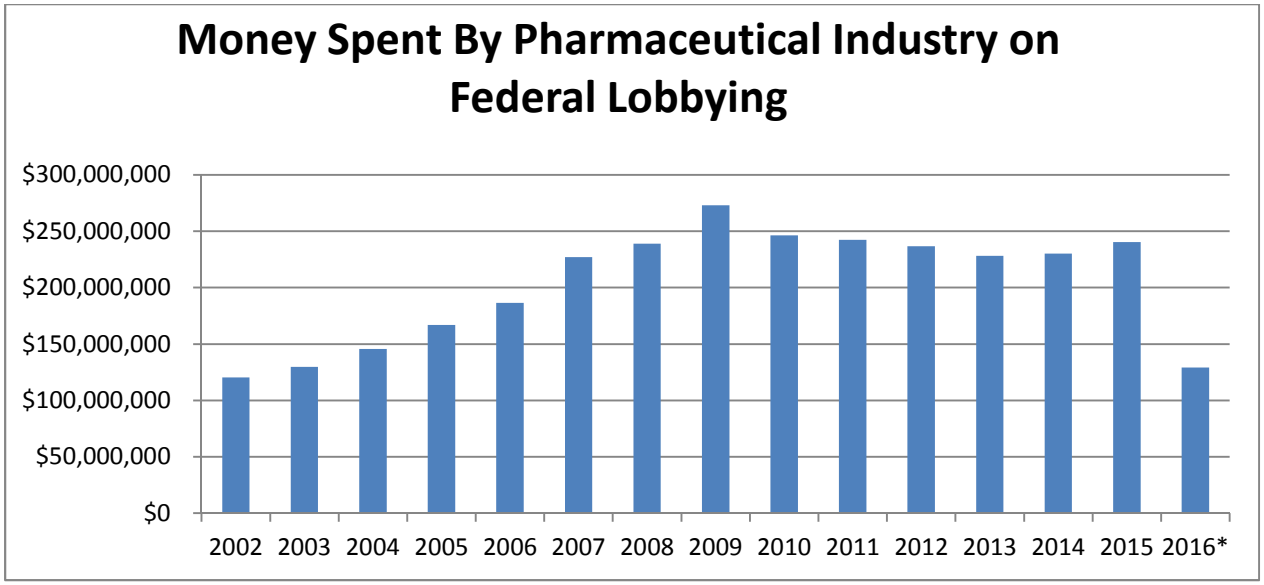
[57] Mylan Q4 2015 Earning Conference Call, Feb. 10, 2016.

effect of this is to harm the competitive process, and not to compete legally in a way that would promote competition or the benefits to consumers from robust and fair competition.

Defendants Manipulate Access to Schools to Enhance and Protect the EpiPen Monopoly

97. Through a carefully orchestrated nationwide lobbying effort on state and federal levels, defendants have created an important sub-market for epinephrine auto-injectors in the nation's public schools, and then excluded competitors from this market through exclusive dealing contracts with those schools. The importance of access to this submarket for nascent competitors is heightened by the unique medical need for this product, and the educational marketing opportunities the submarket affords, as explained in greater detail below.

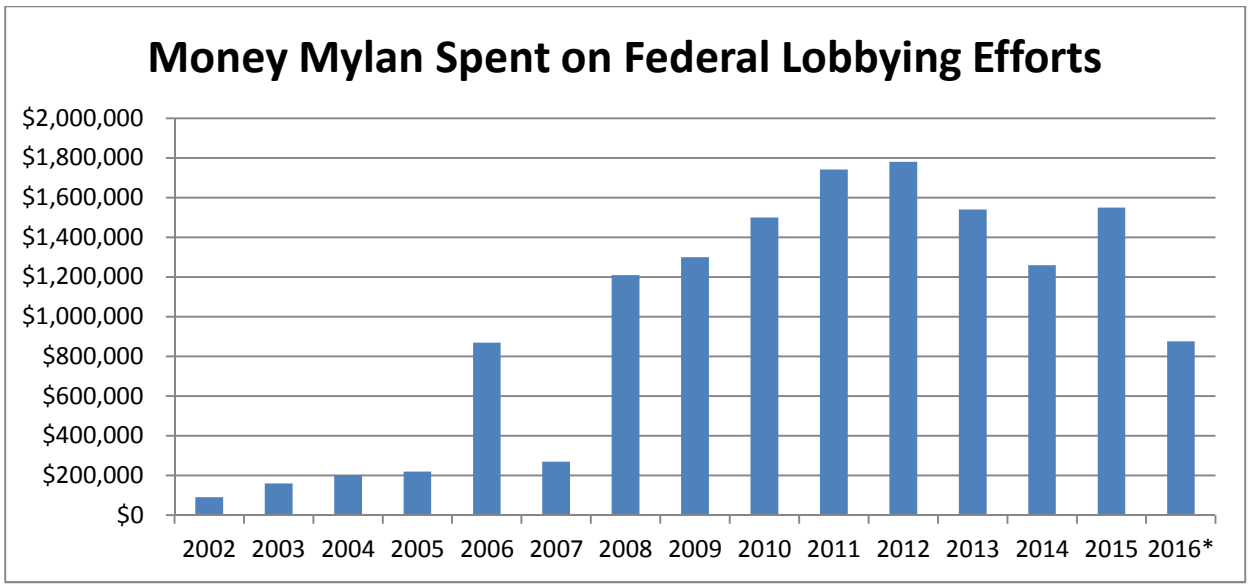
98. The pharmaceutical industry has some of the most active lobbyists on Capitol Hill and in state houses around the country. In fact, the industry regularly spends nearly $250 million a year lobbying Congress.



99. Until recently, however, Mylan had not been among the top spending pharmaceutical lobbying groups. That changed shortly after Mylan purchased the rights to EpiPen.

100. Beginning in 2008, a company that had spent less than $2 million on lobbying in the prior six years combined, upped its federal lobbying budget to $1.2 million. Since then, at a time when industry-wide spending on lobbying has declined, Mylan has spent nearly $12 million

lobbying Capitol Hill alone, and that figure does not account for the considerable funds Mylan has spent lobbying state houses across the country.



101. These lobbying efforts had a primary objective – to gain access to parents, educators and medical professionals by creating a submarket for EpiPens in public schools.

102. That effort has been enormously successful. Today, 37 states ***permit*** their public schools to stockpile epinephrine auto-injectors, and another 11 states actually ***require*** such stockpiling.

103. As the dominant supplier of epinephrine auto-injectors, Mylan's lobbying efforts did not just result in ***access*** to schools, it actually made its product ***mandatory*** for schools in many states.

104. Mylan also spent a reported $4 million specifically lobbying Congress to pass the School Access to Emergency Epinephrine Act, a law that would give federal funding priority to schools that stockpiled epinephrine auto-injectors. President Barrack Obama signed that bill into law in 2013.

105. Adding school districts to the market for auto-injectors created a substantial additional need for EpiPens. There are now more than 67,000 school districts that purchase EpiPens, and they are typically "bulk" purchasers. For example, the public schools in Fairfax

County, Virginia, annually order about 1,100 EpiPen 2-paks each year to have on hand for their 180,000 students.[58]

106. But opening up new markets for the EpiPen was not even the primary advantage of these new laws. Gaining access to school nurses and creating familiarity with the EpiPen among parents has made the product as ubiquitous as Kleenex. As the *Washington Post* recently noted: "Although these legislative efforts were not supposed to benefit a particular company, the brand has such a lock on the market that when President Obama signed the School Access to Emergency Epinephrine Act in 2013, a news announcement simply called it the 'EpiPen Law.'"[59]

107. As the *Washington Post* recognized, while that law gave financial incentives to schools to stock EpiPens, it also allowed "trained school personnel to administer the treatment to students."[60] "'That was a Trojan horse,' said David Morris, a Wells Fargo analyst. 'That was, "Let's get it in schools to help people," but it helps market EpiPen and promote it as the trusted product in schools.'"[61]

108. R. Adams Dudley, a pulmonologist at the University of California at San Francisco, observed:

> [Mylan's] most brilliant maneuver, clearly, was giving them [EpiPens] away to schools and making it the thing that they could say, 'Well, the nurse knows how to use it' . . . What are parents afraid of? Their child will be away from them, and they won't be there to use it. If they can say the school nurse knows how to use an EpiPen; she's never seen an Adrenaclick . . . It's just a fear thing.[62]

109. Thus, Mylan's lobbying efforts expanded its monopoly by creating a critical new submarket for epinephrine auto-injectors in schools. It also created a sales and marketing

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[58] Ike Swetlitz & Ed Silverman, *Mylan may have violated antitrust in its EpiPen sales to schools, legal experts say*, STAT, Aug. 25, 2016, *available at* https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/.

[59] Carolyn Johnson & Catherine Ho, *How Mylan, the maker of EpiPen, became a virtual monopoly*, Washington Post, Aug. 26, 2016.

[60] *Id.*

[61] *Id.*

[62] *Id.*

channel that was invaluable in entrenching its already dominant market position. Access to this market was critical to any nascent competitor that sought, or might seek, to introduce its own epinephrine auto-injectors.

110. Having succeeded in essentially mandating stockpiling of epinephrine auto-injectors in schools, Mylan then acted swiftly to ensure that no other competitor could operate in this new and important space. To ensure this new avenue remained completely out of reach from competition, Mylan gave free and discounted EpiPens to school districts that now had to (or were strongly encouraged to) comply with these new regulations, ***but also made those offers contingent on the schools entering into illegal exclusive dealing agreements with Mylan***.

111. In August 2012, Mylan launched the "EpiPen4Schools" program, which provided EpiPens to schools at a discounted rate. The program, which has grown to include more than 67,000 schools, provided EpiPens to schools at a discounted price of $112.10 in 2015, $350 less than the list price at the time.

112. In order to qualify for this discount, however, schools had to sign a contract agreeing not to purchase any products from Mylan's competitors for a period of 12 months.[63]

113. In addition to providing discounted injectors, the program also provided for free EpiPen sets to be sent to certain schools. As described in one report, "[w]hile this sounds like a generous thing for Mylan to do, we predict that Mylan is simply seeding the schools for automatic replenishment when the product expires."[64]

114. On September 6, 2016, New York Attorney General Eric T. Schneiderman announced the commencement of his office's investigation into Mylan: "A preliminary review by the Office of the Attorney General revealed that Mylan Pharmaceuticals may have inserted

[63] Sen. Blumenthal & Sen. Klobuchar Press Release, *Blumenthal & Klobuchar Call for Immediate Federal Investigation into Possible Antitrust Violations by EpiPen Manufacturer*, Sept. 6, 2016.

[64] BMO Capital Markets, "Mylan: A Generic Generic Company; Initiating With Underperform," May 9, 2013, at 10.

potentially anticompetitive terms into its EpiPen sales contracts with numerous local school systems."[65]

115. As noted antitrust expert Professor Herbert Hovenkamp has stated, use of exclusive dealing contracts while possessing market power can violate the antitrust laws. As reported by *STAT News*:

> "It is illegal to issue a discount on the condition the customer not acquire a competitor's goods – if the effect may be to substantially lessen competition," said Herbert Hovenkamp, a University of Iowa law professor and antitrust expert.
>
> At issue is the notion of an exclusionary contract, which requires a customer to promise not to deal with a competitor. Exclusionary contracts are a common tactic for keeping a lock on a market, Hovenkamp said.
>
> But using such a contract while also having a dominant market share may hinder competition, which he explained can be an antitrust violation. Last year, EpiPen made up 89 percent of the epinephrine auto-injector market, according to IMS Health, a market research firm.[66]

116. Public schools notoriously operate under very strict budgets. In states that now require schools to stockpile epinephrine injectors, that duty comes with a significant cost. Schools in states that permit the stockpiling of auto-injectors also face intense pressure to do so from concerned parents and, in part, out of the potential legal liability that attends a decision ***not*** to stock such potentially life-saving devices in the face of a foreseeable risk posed by the potentially life-threatening allergies of some of their students.

117. Leveraging its dominant market position, Mylan has foreclosed competition in this submarket by offering to supply a portion of each school's need for auto-injectors with free or discounted stock ***in exchange for entering into exclusive dealing contracts with those schools***.

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[65] Press Release, *A.G. Schneiderman Launches Antitrust Investigation Into Mylan Pharmaceuticals Inc., Maker of Epipen*, Sept. 6, 2016, *available at* http://www.ag.ny.gov/press-release/ag-schneiderman-launches-antitrust-investigation-mylan-pharmaceuticals-inc-maker.

[66] Ike Swetlitz & Ed Silverman, *Mylan may have violated antitrust law in its EpiPen sales to schools, legal experts say*, STAT, Aug. 25, 2016, *available at* https://www.statnews.com/2016/08/25/mylan-antitrust-epipen-schools/.

118. By foreclosing this important submarket from its rivals, defendants have harmed competition that affects both the price of auto-injectors and the ability of nascent competitors to introduce competing products in this important environment.

Defendants Extend and Protect the EpiPen Monopoly Through Misuse of Patents and Patent Infringement Litigation

119. Defendants have a unified interest in protecting the EpiPen monopoly. That is because while Pfizer and its subsidiaries own the patents protecting the EpiPen and is the contract supplier of the product, Mylan owns the trademarked brand names and controls the worldwide marketing and sale of the products. Their divided intellectual property ownership of the EpiPen and their licensing agreements for it have caused the two companies to work collaboratively to enhance the products sales volume and profitability. Defendants' EpiPen-related revenues rise (or fall) together. If the EpiPen patents are invalidated, or if other competitors gain market share, both stand to lose, and so they have stood together to fend off competitors and protect the EpiPen patents.

120. Since Mylan acquired the rights to market and sell the EpiPen from Merck in 2007, it has purchased its EpiPens exclusively from King (that supplies the generic epinephrine), and King's subsidiary Meridian (that holds the relevant patents and manufactures the pens).

121. In October 2010, Pfizer purchased King (which owned Meridian) and has acted as Mylan's sole provider of EpiPens ever since.

122. At the time of the Pfizer acquisition, Mylan was rightly concerned that Pfizer might try to compete with Mylan by marketing the same device to consumers under a different trade name.[67] But rather than compete with Mylan, Pfizer agreed to continue supplying the device to Mylan under terms that are not publicly available.

123. On information and belief, that agreement provides for the sale of EpiPens to Mylan at a contract price which has recently escalated along with EpiPen's market dominance, recently rising from roughly $80 per unit to $86 per unit.

[67] *See* Jim Edwards, *In $3.6B King Deal, Pfizer Gets a Small but Important EpiPen Monopoly*, MoneyWatch, Oct. 12, 2010.

124. Pfizer's revenue on sales of the EpiPen has also increased along with Mylan's as EpiPen's market dominance has grown.

Year	Unit Sales Volume of EpiPen	Pfizer's EpiPen Revenue[68]	Unit Price
2012	3,310	$263M	$79.50
2013	3,416	$273M	$80.00
2014	3,656	$294M	$80.00
2015	3,930	$339M	$86.00

Regulatory Framework

125. In 1984, Congress attempted to address the rising costs of prescription drugs by making more readily available bioequivalent generic drugs though passage of the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

126. This Act simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need to file lengthy and costly NDAs to cover bioequivalent drugs. Instead, generic drugs could now be approved through a streamlined and much less expensive ANDA process.

127. The Act also permitted an ANDA to be filed for drugs that are still patent-protected if it is filed under Paragraph IV of the Act. Such a filing challenges the legitimacy of the patent covering the brand name drug.

128. If a patent infringement action is filed within 45 days of the ANDA, then the FDA is not permitted to approve the ANDA until the patent is invalidated through the litigation or 30 months has passed, whichever is earlier.

129. It is well recognized that branded drug manufacturers routinely commence patent infringement litigation against would-be generic competitors in order to invoke the automatic stay and perpetuate their monopoly, regardless of the validity of their patents.[69]

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[68] From Pfizer's Financial Statements, Appendix A, 2012-2015.

[69] Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 Mich. L. Rev. 37 (2009); Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60

130. In addition to filing often baseless patent infringement litigations to stave off generic competition, brand name manufacturers have also developed a practice of entering into "reverse payment settlements" in which brand name manufacturers "pay off" generic competitors in exchange for a delay in generic competition. In other words, the brand name company agrees to share its monopoly profits with the generic, in exchange for the generic agreeing not to enter the market for a period of time. This forces consumers and health insurers to purchase the higher-priced branded product until the agreement settling the patent infringement lawsuit expires.

131. Such exclusion payment agreements among horizontal competitors not to compete are commonly known as "pay-for-delay" or "reverse payment agreements" – reverse payment because the plaintiff in the litigation atypically pays the defendant to resolve the case.

132. Initially, these agreements took the form of a straight cash payment from the brand name manufacturer to the generic competitor. As a result of regulatory scrutiny and congressional investigations, however, brand name manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to mask the fundamentally anticompetitive nature of those agreements.

133. Because the profits to be gained by delaying generic competition are so great, brand name drug manufacturers routinely enter into these "reverse payment agreements" in order to secure and retain monopoly profits for as long as possible.

134. In 2013, the U.S. Supreme Court held that the settlement of a patent infringement suit in which the patentee of a branded pharmaceutical drug gave valuable consideration to a generic to stay out of the market as part of a "reverse payment agreement" could be illegal under the antitrust laws. *FTC v. Actavis, Inc.*, __U.S.__, 133 S. Ct. 2223 (2013).

Hastings L.J. 171 (2008); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553 (2006); Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 Berkeley Tech. L.J. 317 (2002).

The "Evergreening" Problem

135. "Evergreening" is the process of extending patent protection over a drug or medical device. As the original patent protecting the device is about to expire, the patent owner will make a small change to the design and then file an application for a new patent to cover the slightly altered device. The alterations often do nothing to improve the safety or efficacy of the device or drug. Rather, the modifications are made only to permit a new patent to be issued, thus protecting the device or drug from unwanted competition.

136. Even if the new patents can be invalidated, as noted above, those sham patents provide a certain measure of protection, in part because a patent holder can use them to forestall ANDAs and NDAs filed by would-be competitors by triggering provisions of the Hatch-Waxman Act.

137. The first EpiPen patent was acquired in 1977, when patent number US4031893 A was assigned to Survival Technology Inc. Since then, the device has remained patent-protected due to a series of minor device changes that allowed the patent holder to obtain newer patents and thus extend its patent monopoly.[70]

138. For example, in 2007, 2008, 2010, 2011, and 2014, Meridian obtained Patent Numbers D543273S1, US 7,449,012 B2, US 7,794,432 B2, US 8,048,035 B2, and US 8,870,827 B2 respectively. None of these patents represent significant changes in the device, originally patented 33 years earlier, that will meaningfully improve the efficacy or safety of the device, but unless invalidated they will continue to protect the device from generic competition until 2025.

139. As stated in a 2012 analyst report, Mylan "has been taking steps on multiple fronts to stymie generics, including the introduction of a redesigned auto injector in 2009 that offers some incremental safety features and carries additional IP protection."[71] That "new" auto-injector, however, was no different from its predecessor and was introduced essentially to renew patents protecting the EpiPen.

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[70] *See* Roger Collier, *Drug patents: the evergreening problem*, CMAJ, June 11, 2013, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/.

[71] Susquehanna Financial Group, "Mylan, Inc.: A Good Growth Story that Should Have Legs," Mar. 14, 2012, at 12.

Defendants Used this Framework to Fend-Off Would-Be Generic Competition for the EpiPen

140. EpiPen auto-injectors were initially approved for sale by the FDA in 1987. The lifecycle of the EpiPen patent since then reveals how Pfizer and Mylan have for years used evergreened patents, patent infringement litigation and settlements, and citizen petitions to delay entry of a generic EpiPen or novel competing product and further protect its monopoly from competition in the market for epinephrine auto-injectors.

The Teva Litigation

141. In late July 2009, Teva filed ANDA 90-589 with the FDA seeking approval to market a generic EpiPen. Pfizer (through its subsidiaries King and Meridian) promptly responded by filing a patent infringement lawsuit against Teva in August 2009.

142. That lawsuit, *King Pharmaceuticals, Inc. v. Teva Parentaeral Medicines Inc.*, No. 1:09-cv-00652 (D. Del.), alleged infringement of U.S. Patent No. 7,449,012, which is not set to expire until 2025. Pfizer then filed a First Amended Complaint on November 11, 2010 to include a claim of infringement on another auto-injector device patent, U.S. Patent No. 7,794,432.

143. With knowledge that they could not prevail, Pfizer dropped all claims related to infringement of the '012 Patent, leaving only the claims related to the '432 Patent.

144. Following discovery, the case against Teva proceeded to a four-day bench trial in March 2012. The focus of the bench trial was claims 19, 20 and 21 of the '432 Patent.

145. According to Pfizer's counsel, the most important claim terms at issue in the bench trial, all present in claims 19 or 20 of the '432 Patent, were "a first locked retracted position," the claim that "energy released from the stored energy source to drive the needle during the medicament dispensing operation is not transferred to the needle cover," and "attenuating kickback."

146. Teva argued that its generic version of the next-generation epinephrine auto-injector, as submitted in its ANDA, did not infringe the '432 Patent for a number of reasons. ***First***, Teva's generic equivalent relied on manual insertion of the needle into the patient, not requiring "a stored energy source capable of driving the plunger within the cartridge to dispense

the medicament through the needle assembly." ***Second***, Teva's generic equivalent did not have a needle cover that locks in place, as opposed to the '432 Patent which requires "the needle cover having a first locked retracted position." ***Third***, Teva's generic equivalent did not have energy released from the stored energy source, in direct contradiction to the claims of the '432 Patent.

147. In addition to the obvious differences in Teva's auto-injector, as well as favorable claim constructions by the court, the bench trial included evidence of three pieces of "prior art references" which Teva contended invalidated the '432 Patent.

148. Before the trial concluded, however, on April 27, 2012, Mylan and Pfizer issued a joint press release announcing they had settled the action, and as a part of the settlement Teva would not begin marketing a generic version of the EpiPen auto-injector until June 2015. As a result of the settlement and regulatory framework of the Hatch-Waxman Act, defendants and Teva foreclosed entry by any other generic EpiPen auto-injectors from the market until 180 days after Teva's generic release in June 2015.

149. No rational economic actor with a viable product would refrain from entering a lucrative "blockbuster" market unless they received some form of valuable consideration.

150. Upon information and belief, Teva received unjustifiable consideration, incentives and benefits in exchange for its agreement to delay its, and other potential generic EpiPen auto-injectors, from reaching the market before June 2015, and/or roughly January 2016, respectively.

151. But, as Teva's June 2015 generic entry loomed, Mylan reached into its toolkit to pull out a citizen petition,[72] which it filed on January 16, 2015, a mere six months before Teva was scheduled (pursuant to the settlement) to enter the market.[73] In other words, even though the parties had already agreed through settlement to delay Teva's generic entry for more than three

[72] Ninety-two percent of citizen petitions between 2011 and 2015 were filed by name brand drug manufacturers, and the FDA denied more than nine out of every ten petitions. In its Eighth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions for 2015 to Congress, the FDA noted that most citizen petitions do not raise valid scientific concerns and appear to have been filed to delay approval of competing medicines.

[73] Citizen Petition From Milan Specialty, L.P., No. FDA-2015-P-0181-0001 (Jan. 16, 2015), *available at* https://www.regulations.gov/document?D=FDA-2015-P-0181-0001. Mylan may have known about Teva's ANDA as early as 2008. *See* Carrier & Minniti, 102 Cornell L. Rev. Online at 65.

years, defendants sought to ***further*** delay the entry of Teva's generic through Mylan's citizen petition.

152. A key part of Mylan's petition was the argument that anything other than an identical product may make it difficult for patients in an emergency situation to use a generic safely and effectively in keeping with instructions for EpiPen.[74] Thus, in addition to evergreening the EpiPen patents and taking repeated steps to thwart any challenges to the validity of those patents, Mylan argued that anything other than an exact replica of its product should not be approved. In other words, because EpiPen's market dominance had made the device as ubiquitous as "Kleenex," largely through Mylan's lock-down of the school sub-market for auto-injectors (as described above), ***no other competing device design should ever be approved***.

153. In connection with its citizen petition, Mylan also submitted a statement from Dr. Eli Meltzer, an allergist in San Diego, who declared that "I do not believe that a user trained on the EpiPen . . . platform will be able to reliably use a different operational platform in an emergency situation as safely and effectively." As noted by *NBC News*, which first reported about the citizen petition and the study, Meltzer was paid roughly $95,000 in fees in 2014 and 2015 by Mylan, according to the OpenPayments federal database.[75]

154. After Mylan filed its petition, the FDA had 150 days to respond to it, and that deadline coincided with the time when the patent settlement allowed Teva to begin selling a generic. But in May 2015, ***five months after it filed its citizen petition***, Mylan supplemented its petition with a report[76] from a consulting firm that gave the generic device to patients and concluded they were not using the Teva product correctly and, therefore, it would not be effective.

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[74] Ex Silverman, *How Mylan tried to keep Teva from selling a generic EpiPen*, STAT, Aug. 31, 2016, *available at* https://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/.

[75] *See* https://openpaymentsdata.cms.gov/search.

[76] Interface Analysis Associates, *Generic Epinephrine Auto-Injector Handling Study*, Apr. 21, 2015.

155. By filing the supplement, defendants presumably hoped to ***further*** extend the time the FDA would need to review its entire petition. Ultimately, the FDA rejected the Teva product in February 2016 due to unspecified deficiencies.

156. Given that Teva's generic had been in development for at least ***six years*** before the petition's filing,[77] this late filing of a supplemental study implicates significant timing questions. Why would such a study be submitted only weeks before the FDA was required to respond under the FDA's 150-day clock?[78]

157. Even though Teva's ANDA ultimately was denied,[79] the petition still raises significant concern since Mylan: (a) could not have known at the time of filing that the FDA would deny the application; and (b) increased the likelihood of delay through its stalled petition and supplemental filing.

The Sandoz Litigation

158. In May 2010, Sandoz submitted an ANDA pursuant to Paragraph IV with the FDA to obtain approval to market a generic version of the EpiPen.

159. On July 24, 2010, King filed a patent infringement lawsuit again Sandoz. By filing the patent infringement lawsuit, defendants again sought to trigger the 30-month stay of the ANDA application pursuant to the Hatch-Waxman Act.

160. As in the prior litigation with Teva, King alleged the Sandoz application infringed the '012 Patent. That case, however, was stayed indefinitely in May 2011 and remains in hibernation today.

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[77] *See* Carrier & Minniti, 102 Cornell L. Rev. Online at 63-64.

[78] The study also apparently "'had a lot of problems'" as it "lacked a control group; did not study the actual generic but a prototype instead; used a small number of participants; failed to provide them with proper instructions for use; and told participants to watch a video rather than actually use the Teva device." Ed Silverman, *How Mylan tried to keep Teva from selling a generic EpiPen*, STAT, Aug. 31, 2016, *available at* https://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/.

[79] Carly Helfand, *FDA swats down Teva's EpiPen copy, putting Mylan in cruise control*, FiercePharma, Mar. 1, 2016, *available at* http://www.fiercepharma.com/sales-and-marketing/fda-swats-down-teva-s-epipen-copy-putting-mylan-cruise-control.

161. Staying the litigation also stays any definitive ruling on a challenge to the EpiPen patents. On information and belief, defendants entered into an agreement with Sandoz to stay the case indefinitely in exchange for valuable consideration to Sandoz.

The Intellijject Litigation

162. Yet another example of defendants' abuse of patent litigation to protect their EpiPen monopoly are their actions against Intellijject, the inventor of the Auvi-Q, when that company sought approval for an EpiPen competitor device.

163. Intellijject is a company that was essentially founded on a single venture, creation of epinephrine auto-injector that would compete with the EpiPen. Rather than pursue a generic version, Intellijject sought to create its own unique delivery device.

164. On November 30, 2009, pharmaceutical giant Sanofi-Aventis ("Sanofi") announced it had obtained the rights to Intellijject's epinephrine auto-injector and that under the license, Sanofi would be responsible for the manufacturing and commercialization of the product while Intellijject would be responsible for the ongoing development and for obtaining regulatory approval.

165. With Sanofi now providing financial and marketing support, Intellijject's prospects for developing a competing epinephrine auto-injector became very real for defendants.

166. When the Intellijject device, dubbed the e-cue (and later renamed Auvi-Q), was ready to embark on the approval process, Intellijject submitted an NDA (not an ANDA) with the FDA on September 29, 2010.

167. They did not pursue approval through the more streamlined ANDA process because the EpiPen and the e-cue were very different devices, both in appearance and operation.

168. The EpiPen is a device shaped like a writing pen, with a safety cap on one end and a spring-loaded needle on the other end. In order to activate the EpiPen, the safety cap must be removed and the end with the spring-loaded needle pressed against the thigh.

169. E-cue, on the other hand, was shaped flat and rectangular, like a credit card, and incorporated a safety tab mechanism on the needle end of the device. The e-cue also used a voice prompt system that provided step-by-step instructions on how to use the device in order to

prevent accidental needle sticks. The device also does not require a safety cap because its needle retracts, requires less piercing time (less than 1 second compared to 5 seconds for EpiPen), and is less painful because its needle is designed to pierce the skin at exactly 90 degrees.

170. Not content to simply compete with a new auto-injector rival, however, defendants, through King, filed a patent infringement lawsuit against Intellijject on January 19, 2011 to block FDA approval of its NDA.

171. King alleged the e-cue device infringed the '432 Patent, entitled "Automatic Injector with Kickback Attenuation." As noted above, that patent was not obtained by Meridian until September 14, 2010, ***well over a year after Intellijject began development of the e-cue and only two weeks before Intellijject filed its NDA***.

172. Meridian filed the '432 Patent in the Orange Book on September 15, 2010, ***the very day after it was issued*** by the Patent Trademark Office. The alacrity with which Meridian filed the '432 Patent in the Orange Book was inconsistent with its prior history. For example, the '012 Patent was not filed in the Orange Book for more than eight months after the patent was granted. On information and belief, Meridian rushed to submit the '432 Patent in the Orange Book before Intellijject filed its NDA.

173. On August 1, 2011, Intellijject announced the FDA had given the e-cue tentative final approval. According to Intellijject's press release:

> Obtaining a tentative approval means that the product review is complete and the submission met the FDA's requirements to be approved. The FDA reserves final approval of the product, however, until all exclusivity or patent challenges have been resolved, specifically the current patent litigation brought against Intellijject by King Pharmaceuticals, Inc. (King) and Meridian Medical Technologies, Inc. (Meridian). Final FDA approval is required before a product can be marketed in the United States.

174. Meanwhile, defendants' patent litigation dragged on for another six months.

175. On February 16, 2012, Mylan and Pfizer (again jointly) announced they had reached a settlement with Intellijject over their patent litigation. Although the terms of that deal are confidential, the parties did reveal that the agreement prevented Intellijject and Sanofi from launching their e-cue device for another nine months, until November 15, 2012. The relatively

short duration of delay before entry of the e-cue likely indicates the strength of Intellijject's defenses to the patent litigation.

176. Nevertheless, on information and belief, Intellijject and Sanofi agreed not to enter the market until November 15, 2012 in exchange for valuable consideration.

177. On August 10, 2012, the FDA granted final approval of Intellijject's NDA, but pursuant to the settlement consumers would not have access to the e-cue until November 2012.

178. This consistent pattern of using sham patent litigation and reverse payment settlements to delay and forestall entry of competitors, along with their evergreening of the EpiPen patents, further demonstrates defendants' improper acquisition and maintenance of their monopoly.

Mylan's History of Anticompetitive Conduct in Other Markets Betrays Its True Motives Regarding EpiPen

179. In addition to its track record of misusing patents to protect its monopoly, Mylan has a history of leveraging its dominant market position to extract exclusive dealing agreements and then hiking the price of drugs it monopolizes, just as it has done with the EpiPen.

180. In 1998, the Federal Trade Commission ("FTC") and 32 states filed suit against Mylan and four other companies alleging Mylan leveraged its dominant market position to extract exclusive dealing agreements from three of the defendants that supplied the Active Pharmaceutical Ingredient ("API") used to manufacture two generic drugs – lorazepam and clorazepate.

181. In exchange for these exclusive dealing agreements, Mylan offered to share a percentage of its gross profits with the other defendants. In so doing, the FTC and state attorneys general alleged that Mylan effectively denied its competitors access to the most important ingredient for producing these drugs.

182. The states also alleged Mylan tried to enter into an exclusive licensing agreement with the fourth defendant to control the distribution of lorazepam made with an alternative API, a formulation Mylan did not even have FDA approval yet to sell. The states alleged that Mylan's attempt to control the supply of that alternate formulation, when it was not yet approved to sell it, further demonstrated the anticompetitive nature of Mylan's actions.

183. The complaints averred that after securing the exclusive dealing agreements, Mylan raised the price of clorazepate tablets in amounts ranging from 1,900% to over 3,200%, and raised the price of lorazepam tablets by amounts ranging from 1,900% to 2,600%.

184. In 2001, the FTC and the 32 states announced they had reached a settlement of the action which included substantial injunctive relief and Mylan's agreement to create two settlement funds totaling $100 million to compensate consumers for the overcharges.

Mylan's History of Other Bad Acts Is Repeating Itself Through Sales of the EpiPen

185. In addition to repeating its pattern of using exclusive dealing agreements to choke off competition and then leveraging its monopoly power to significantly raise prices, Mylan has a history of manipulating Medicaid's Medical Drug Rebate Program ("MDRP") to extract higher payments for what are actually "generic" drugs.

186. On September 28, 2016, Senators Richard Blumenthal, Chuck Grassley and Amy Klobuchar sent a letter to U.S. Attorney General Loretta Lynch inquiring whether the U.S. Department of Justice ("DOJ") had considered an investigation into whether Mylan violated the law when it apparently misclassified its EpiPen for purposes of the MDRP.[80]

187. As explained in the letter, Congress created the MDRP to help protect states from high pharmaceutical prices by requiring drug companies to pay a percentage of their revenues to states in the form of rebates. Companies pay a rebate of only 13% for non-innovator (generic) drugs, but must pay at least 23.1% for innovator (brand name) drugs.

188. The Senators noted that Mylan might have known that EpiPen should be classified as a non-innovator drug, in part, based on its aggressive enforcement of its own patent-protected monopoly over the EpiPen, as evidenced by the actions it took against Teva, Sandoz, Intelliject and Sanofi, as described above.

189. On October 7, 2016, Mylan announced it had reached a $465 million settlement with the DOJ resolving an investigation by the DOJ into whether Mylan manipulated the

[80] Letter from Senators Richard Blumenthal, Chuck Grassley & Amy Klobuchar to Attorney General Loretta E. Lynch, Sept. 28, 2016, *available at* http://www.grassley.senate.gov/news/news-releases/senators-ask-justice-department-consider-investigating-mylans-medicaid-rebates.

classification of EpiPens covered by Medicaid. The DOJ, however, has not announced such a settlement, the details of which appear to be still in negotiation.

190. This misconduct regarding rebates repeats a pattern of such abuses that harkens back to a 2009 settlement Mylan reached with the DOJ over similar manipulations of Medicaid payments for covered generic drugs.

191. In 2009, the DOJ announced that Mylan and several other companies had "agreed to pay a settlement to resolve allegations that [they] had sold innovator drugs that were manufactured by other companies and had classified those drugs as non-innovator drugs for Medicaid rebate purposes. As a result of the improper classification of these drugs, the companies underpaid their rebate obligations under the Medicaid Rebate Program."[81]

192. The DOJ press release went on to explain:

> Mylan and UDL agreed to pay $118 million to resolve allegations that they underpaid their rebate obligations with respect to several Mylan drugs (nifedipine extended release tablets, flecainide acetate, selegiline HCL, Orphenadrine Citrate Aspirin and Caffeine tablets, Triamterene/Hydrochlorothiazide, Propoxyphene HCL, Propoxyphene HCL/Aspirin/Caffeine, Prophyxphene Napsylate/Acetaminophen, Ibuprofen tablets, Bumetanide, Cephalexin and Cefactor) and several UDL drugs (nifedipine extended release tablets, selegiline HCL, Triamterene & HCTZ, Propox Naps & APAP, Flecainide Acetate, Trihexyphenidyl, Ranitidine HCL syrup, Sucralfate Suspension, Selegiline HCL and Bumetanide). Because the Medicaid program is funded by both the federal and state governments, the federal government received $60,896,476.00, the states $49,824,389.00 of the settlement amount and $7,279,135.00 will be paid to entities that participated in the Public Health Service's Drug Pricing Program.

193. These past and present actions further demonstrate that Mylan's overly aggressive tactics of dominating the market for EpiPens and then milking consumers and third-party payors for every cent of profit it can extract, legally or otherwise, is simply consistent with its past practices.

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[81] U.S. Department of Justice Press Release, *Four Pharmaceutical Companies Pay $124 Million for Submission of False Claims to Medicaid*, Oct. 19, 2009, *available at* https://www.justice.gov/opa/pr/four-pharmaceutical-companies-pay-124-million-submission-false-claims-medicaid.

INTERSTATE AND INTRASTATE COMMERCE

194. At all material times, defendants manufactured, promoted, distributed, and sold a substantial number of EpiPens in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

195. At all material times, defendants transmitted funds, as well as contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of EpiPens.

196. In furtherance of their efforts to monopolize and restrain competition in the market for epinephrine auto-injectors, defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. The activities of defendants were within the flow of and have substantially affected interstate commerce.

197. Defendants' anticompetitive conduct has substantial intrastate effects in that, *inter alia*, consumers and third-party payors within each state have paid uncompetitive prices for EpiPens that would have and should have been lower but for defendants' anticompetitive conduct. Defendants' conduct has affected interstate and intrastate commerce in each of the states.

MARKET EFFECTS AND DAMAGES TO THE CLASS

198. As alleged herein, the prices for EpiPen began increasing following Mylan's acquisition of EpiPen in 2007. Further, as Figure 1 above demonstrates, these prices began increasing significantly in 2009 following: (a) the reintroduction of a "new" EpiPen and the evergreening of the EpiPen patents; and (b) the lawsuit Mylan filed against Teva for patent infringement.

199. These prices have continued to significantly increase through the present at rates that could not be explained by production costs. As a result of the conduct alleged herein, Mylan was able to charge prices for EpiPen that were higher than it otherwise would have been able to in the absence of the alleged misconduct.

200. Defendants' exclusion payment agreements had the purpose and effect of restraining competition unreasonably and injuring competition by protecting EpiPen from generic competition. Defendants' actions allowed them to maintain a monopoly and to exclude competition in the market for epinephrine auto-injectors, to the detriment of plaintiffs and all other members of the Class.

201. Moreover, due to defendants' exclusion payment agreements and the overarching scheme alleged herein, other generic manufacturers were discouraged from and/or delayed in (a) developing generic versions of the EpiPen, and/or (b) challenging the validity or infringement of the EpiPen patents in court.

202. During the Class Period (defined herein), plaintiffs and other members of the Class purchased a substantial number of EpiPens. As a result of defendants' illegal conduct as alleged herein, plaintiffs and other members of the Class were compelled to pay, and did pay, artificially inflated prices for those EpiPens. Plaintiffs and the other Class members paid prices for EpiPens that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) Class members were deprived of the opportunity to purchase lower-priced generic EpiPens; and (b) Class members paid artificially inflated prices for their EpiPens.

203. As a consequence, plaintiffs and other members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

204. Thus, defendants' unlawful conduct deprived plaintiffs and the Class of the benefits of competition that the antitrust laws were designed to ensure.

ANTITRUST IMPACT

205. During the relevant period, plaintiffs and members of the Class purchased EpiPens indirectly from defendants. As a result of defendants' illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their EpiPens. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because the price of EpiPens was artificially inflated by

defendants' illegal conduct, and Class members were deprived of the opportunity to purchase lower-priced generic versions of EpiPens.

206. As a consequence, plaintiffs and members of the Class have sustained substantial losses in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

207. General economic theory recognizes that any overcharge at a higher level of distribution generally results in higher prices at every level below.

208. Wholesalers and retailers passed on the inflated prices of EpiPens to the Class.

209. Defendants' anticompetitive actions enabled them to indirectly charge consumers and third-party payors prices in excess of what they otherwise would have been able to charge absent their unlawful actions.

210. The prices were inflated as a direct and foreseeable result of defendants' anticompetitive conduct.

211. The inflated prices the Class paid are traceable to, and the foreseeable result of, defendants' conduct.

CLASS ACTION ALLEGATIONS

212. Plaintiffs bring this action on behalf of themselves and, under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3), as representatives of a Class defined as follows:

> All persons or entities in the United States and its territories who purchased and/or paid for some or all of the purchase price for EpiPen(s), for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"), other than for resale, during the period 2009 through and until the anticompetitive effects of defendants' unlawful conduct cease (the "Class Period"). For purposes of the Class definition, persons or entities "purchased" EpiPen(s) if they paid or reimbursed some or all of the purchase price.

213. The following persons or entities are excluded from the proposed Class:

(a) Defendants and their officers, directors, management, employees, subsidiaries or affiliates;

(b) All governmental entities, except for governmental funded employee benefit plans;

(c) All persons or entities who purchased EpiPen(s) for purposes of resale or directly from defendants or their affiliates;

(d) Fully insured health plans (*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members);

(e) Any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; and

(f) The judges in this case and any members of their immediate families.

214. Members of the Class are so numerous that joinder is impracticable. Plaintiffs believe that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

215. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and all members of the Class were damaged by the same wrongful conduct of defendants, *i.e.*, they paid artificially inflated prices for EpiPen(s) and were deprived of the benefits of earlier and more robust competition from cheaper alternatives as a result of defendants' wrongful conduct.

216. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of the plaintiffs are coincident with, and not antagonistic to, those of the Class.

217. Plaintiffs are represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

218. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in defendants' wrongful conduct.

219. Questions of law and fact common to the Class include, but are not limited to:

(a) Whether defendants had monopoly power in the market for epinephrine injectors during some or all of the Class Period;

(b) Whether defendants willfully maintained and/or enhanced its monopoly power over epinephrine injectors;

(c) Whether defendants used its monopoly power to suppress competition in the market for epinephrine injectors;

(d) Whether defendants entered into illegal exclusive dealing contracts;

(e) Whether the law requires definition of a relevant market when direct proof of monopoly power is available and, if so, the definition of the relevant market;

(f) Whether the activities of defendants as alleged herein have substantially affected interstate commerce;

(g) Whether, and to what extent, defendants' conduct caused antitrust injury (*i.e.*, overcharges) to plaintiffs and the members of the Class; and

(h) The quantum of aggregate overcharge damages to the Class.

220. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

221. Plaintiffs know of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

COUNT I

Claim for Relief For Violations of §§1 and 2 of the Sherman Act Against All Defendants

222. Plaintiffs reallege and incorporate the preceding allegations of this Complaint with the same force and effect as if fully restated herein.

223. Plaintiffs bring this case under §16 of the Clayton Act (15 U.S.C. §26) individually and on behalf of the Class.

224. Defendants knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to block and delay entry of competing epinephrine auto-injectors. The intended and accomplished goal of the scheme was to maintain Mylan's monopoly power using restrictive and exclusionary conduct to delay FDA approval of competing products. Such conduct injured plaintiffs and the Class.

225. It was defendants' conscious objective to further Mylan's monopoly in the relevant market through the overarching anticompetitive scheme. Defendants conspired to monopolize, and did wrongfully and intentionally maintain monopoly power, with respect to the EpiPen epinephrine auto-injector, in violation of §2 of the Sherman Act (15 U.S.C. §2) . As a result of this unlawful maintenance of monopoly power, plaintiffs and members of the Class paid artificially inflated prices.

226. Had manufacturers of competing epinephrine auto-injectors entered the market and lawfully competed with the EpiPen in a timely fashion, plaintiffs and other members of the Class would have substituted lower-priced competing products for the higher-priced brand name EpiPen for some or all of their epinephrine auto-injector requirements, and/or would have paid lower net prices on their remaining epinephrine auto-injector purchases.

227. By their agreement, defendants intentionally and wrongfully conspired and combined in an unreasonable restraint of trade in a *per se* violation of §1 of the Sherman Act (15 U.S.C. §1). As a result of this unreasonable restraint on competition, plaintiffs and members of the Class paid artificially inflated prices for their epinephrine auto-injector requirements.

228. Plaintiffs and members of the Class purchased substantial amounts of EpiPen epinephrine auto-injectors indirectly from Mylan.

229. Plaintiffs and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §2201(a), hereby seek a declaratory judgment that defendants' conduct in seeking to prevent competition as described herein violates §§1 and 2 of the Sherman Act (15 U.S.C. §§1 and 2).

230. Plaintiffs and the Class further seek equitable and injunctive relief pursuant to §16 of the Clayton Act (15 U.S.C. §26), and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of defendants, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

COUNT II

Claim for Relief For Violations of §2 of the Sherman Act Against All Defendants for Conspiracy to Monopolize

231. Plaintiffs reallege and incorporate the preceding allegations of the Complaint with the same force and effect as if fully restated herein.

232. In addition to defendants' violations of §1 of the Sherman Act (15 U.S.C. §1), defendants and their co-conspirators combination, conspiracy and/or contracts to monopolize the epinephrine auto-injector market in the United States and its territories in violation of 15 U.S.C. §2.

233. Defendants deliberately entered into the conspiracy alleged with the specific intent to achieve an unlawful monopoly in the epinephrine auto-injector market, as set forth herein.

234. Defendants' and their co-conspirators' conduct, as described in this Complaint, committed overt acts in furtherance of their unlawful conspiracy.

235. As a direct and proximate result of the conspiracy to monopolize, defendants have restrained competition and injured plaintiffs and each Class member in their business and property in that each has paid a higher price for epinephrine auto-injectors than would have been paid absent defendants' concerted unlawful activity.

COUNT III

Claim for Monopolization Under State Law Against All Defendants

236. Plaintiffs reallege and incorporate the preceding allegations of this Complaint with the same force and effect as if fully restated herein.

237. At all relevant times, Mylan possessed substantial market power (*i.e.*, monopoly power) in the epinephrine auto-injector market. Mylan possessed the power to control prices in,

prevent prices from falling in, and exclude competitors from the epinephrine auto-injector market.

238. Through the overarching anticompetitive scheme, as alleged above, Mylan willfully maintained its monopoly power in the epinephrine auto-injector market using restrictive or exclusionary conduct, rather than by means of greater business acumen, in order to exclude competition for its monopolized EpiPen products.

239. The goal, purpose and effect of Mylan's scheme was to prevent and delay the sale of epinephrine auto-injector products in the United States at prices substantially below Mylan's prices for EpiPen, thereby effectively preventing the average market price of epinephrine auto-injector products from declining dramatically.

240. By engaging in the foregoing conduct, Mylan has violated the following states' antitrust and/or unfair and deceptive trade practices acts:

(a) *Puerto Rico*: The aforementioned practices by defendants were and are in violation of the Puerto Rico Antitrust Act, P.R. Laws Ann. tit. 10, §257 *et seq.*;

(b) *Alabama*: The aforementioned practices by defendants were and are in violation of Ala. Code §6-5-60 *et seq*.

(c) *Arizona*: The aforementioned practices by defendants were and are in violation of the Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. §44-1401 *et seq*., and the Constitution of the State of Arizona, Article 14, §15;

(d) *California*: The aforementioned practices by defendants were and are in violation of the Cartwright Act, Cal. Bus. & Prof. Code §16700 *et seq*.;

(e) *District of Columbia*: The aforementioned practices by defendants were and are in violation of the District of Columbia Antitrust Act, D.C. Code §28-4501 *et seq*.;

(f) *Illinois*: The aforementioned practices by defendants were and are in violation of the Illinois Antitrust Act, 740 Ill. Comp. Stat. 10/1 *et seq*.;

(g) *Iowa*: The aforementioned practices by defendants were and are in violation of the Iowa Competition Law, Iowa Code §553.1 *et seq*.;

(h) *Kansas*: The aforementioned practices by defendants were and are in violation of the Kansas Monopolies and Unfair Trade Act, Kan. Stat. Ann. §50-101 *et seq.*;

(i) *Maine*: The aforementioned practices by defendants were and are in violation of the Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, §1101 *et seq.*;

(j) *Michigan*: The aforementioned practices by defendants were and are in violation of the Michigan Antitrust Reform Act, Mich. Comp. Laws §445.771 *et seq.*;

(k) *Minnesota*: The aforementioned practices by defendants were and are in violation of the Minnesota Antitrust Law of 1971, Minn. Stat. §325D.49 *et seq.*;

(l) *Mississippi*: The aforementioned practices by defendants were and are in violation of Miss. Code Ann. §75-21-1 *et seq.*;

(m) *Nebraska*: The aforementioned practices by defendants were and are in violation of Neb. Rev. Stat. §59-801 *et seq.*;

(n) *Nevada*: The aforementioned practices by defendants were and are in violation of the Nevada Unfair Trade Practice Act, Nev. Rev. Stat. §598A.010 *et seq.*;

(o) *New Mexico*: The aforementioned practices by defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §57-1-1 *et seq.*;

(p) *New York*: The aforementioned practices by defendants were and are in violation of N.Y. Gen. Bus. Law §340 *et seq.*;

(q) *North Carolina*: The aforementioned practices by defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §75-1 *et seq.*;

(r) *North Dakota*: The aforementioned practices by defendants were and are in violation of the North Dakota Antitrust Act, N.D. Cent. Code §51-08.1-01 *et seq.*;

(s) *Oregon*: The aforementioned practices by defendants were and are in violation of Or. Rev. Stat. §646.725 *et seq.*;

(t) *Rhode Island*: The aforementioned practices by defendants were and are in violation of the Rhode Island Antitrust Act, R.I. Gen. Laws §6-36-1 *et seq.*;

(u) *South Dakota*: The aforementioned practices by defendants were and are in violation of South Dakota's antitrust law, S.D. Codified Laws §37-1-3.1 *et seq.*;

(v) *Tennessee*: The aforementioned practices by defendants were and are in violation of the Tennessee Trade Practices Act, Tenn. Code Ann. §47-25-101 *et seq.*;

(w) *Utah*: The aforementioned practices by defendants were and are in violation of the Utah Antitrust Act, Utah Code §76-10-3101 *et seq.*;

(x) *Vermont*: The aforementioned practices by defendants were and are in violation of Vt. Stat. Ann. tit. 9, §2451 *et seq.*;

(y) *West Virginia*: The aforementioned practices by defendants were and are in violation of the West Virginia Antitrust Act, W. Va. Code §47-18-1 *et seq.*; and

(z) *Wisconsin*: The aforementioned practices by defendants were and are in violation of the Wisconsin Antitrust Act, Wis. Stat. §133.01 *et seq*.

241. Plaintiffs and members of the Class have been injured in their business or property by reason of Mylan's antitrust violations alleged in this Count. Their injuries consist of: (a) being denied the opportunity to purchase lower-priced epinephrine auto-injectors sooner; and (b) paying higher prices for EpiPen than they would have paid in the absence of Mylan's conduct. These injuries are the type the antitrust laws were designed to prevent, and flow from that which makes Mylan's conduct unlawful.

242. Plaintiffs and the Class seek damages and multiple damages as permitted by law for their injuries by Mylan's violations of the aforementioned statutes.

COUNT IV

Violation of State Consumer Protection Laws Against All Defendants

243. Plaintiffs reallege and incorporate the preceding allegations of this Complaint with the same force and effect as if fully restated herein.

244. As alleged herein, defendants are able to monopolize the epinephrine auto-injector market by engaging in an anticompetitive scheme to keep generic equivalents from the market – not as a result of providing a superior product, business acumen, or historical accident.

245. The agreement between defendants to monopolize the epinephrine auto-injector market includes overt acts between separate economic entities and is illegal under state and federal antitrust laws.

246. Defendants knowingly and intentionally conspired to maintain and enhance Mylan's monopoly power in the epinephrine auto-injector market. Defendants specifically intended that the overarching anticompetitive scheme would maintain Mylan's monopoly power in the relevant market thereby injuring plaintiffs and the Class.

247. Each defendant committed at least one overt act in furtherance of the conspiracy.

248. Defendants' conduct described herein constitutes unlawful acts of monopolization and attempts to monopolize, as well as prohibited practices of misleading, deceptive, unfair and other unconscionable conduct, under the following state statutes:

(a) *Puerto Rico*: The aforementioned practices by defendants were and are in violation of the Puerto Rico Antitrust Act, P.R. Laws Ann. tit. 10, §257 *et seq.*;

(b) *Arizona*: The aforementioned practices by defendants were and are in violation of the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §44-1521 *et seq.*;

(c) *Arkansas*: The aforementioned practices by defendants were and are in violation of the Arkansas Deceptive Trade Practices Act, Ark. Code Ann. §4-88-101 *et seq.*;

(d) *California*: The aforementioned practices by defendants were and are in violation of the California Unfair Competition Act, Cal. Bus. & Prof. Code §17200 *et seq.*;

(e) *District of Columbia*: The aforementioned practices by defendants were and are in violation of D.C. Code §28-3901 *et seq.*;

(f) *Florida*: The aforementioned practices by defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. §501.201 *et seq.*;

(g) *Hawaii*: The aforementioned practices by defendants were and are in violation of Haw. Rev. Stat. §480-1 *et seq.*;

(h) *Idaho*: The aforementioned practices by defendants were and are in violation of the Idaho Consumer Protection Act, Idaho Code §48-601 *et seq.*;

(i) *Illinois*: The aforementioned practices by defendants were and are in violation of Illinois' Consumer Fraud and Business Practices Act, 815 Ill. Comp. Stat. 505/1 *et seq.*;

(j) *Kansas*: The aforementioned practices by defendants were and are in violation of the Kansas Consumer Protection Act, Kan. Stat. Ann. §50-623 *et seq.*;

(k) *Kentucky*: The aforementioned practices by defendants were and are in violation of Ky. Rev. Stat. §367.110 *et seq.*;

(l) *Massachusetts*: The aforementioned practices by defendants were and are in violation of Massachusetts' Regulation of Business Practice and Consumer Protection Act, Mass. Gen. Laws ch. 93A, §1 *et seq.*;

(m) *Michigan*: The aforementioned practices by defendants were and are in violation of the Michigan Consumer Protection Act, Mich. Comp. Laws §445.901 *et seq.*;

(n) *Minnesota*: The aforementioned practices by defendants were and are in violation of the Minnesota Consumer Fraud Act, Minn. Stat. §325F.68 *et seq.*;

(o) *Missouri*: The aforementioned practices by defendants were and are in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. §407.025;

(p) *Nebraska*: The aforementioned practices by defendants were and are in violation of Nebraska's Consumer Protection Act, Neb. Rev. Stat. §59-1601 *et seq.*;

(q) *Nevada*: The aforementioned practices by defendants were and are in violation of the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. §598.0903 *et seq.*;

(r) *New Jersey*: The aforementioned practices by defendants were and are in violation of N.J. Stat. Ann. §56:8-1 *et seq.*;

(s) *New Mexico*: The aforementioned practices by defendants were and are in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. §57-1-1 *et seq.*, and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §57-12-1 *et seq.*;

(t) *New York*: The aforementioned practices by defendants were and are in violation of N.Y. Gen. Bus. Law §349 *et seq.*;

(u) *North Carolina*: The aforementioned practices by defendants were and are in violation of North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. §75-1 *et seq.*;

(v) *Ohio*: The aforementioned practices by defendants were and are in violation of Ohio Rev. Code Ann. §1345.01 *et seq.*;

(w) *Pennsylvania*: The aforementioned practices by defendants were and are in violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §201-1 *et seq.*;

(x) *Rhode Island*: The aforementioned practices by defendants were and are in violation of R.I. Gen. Laws §6-13.1-1 *et seq.*;

(y) *Vermont*: The aforementioned practices by defendants were and are in violation of the Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, §2451 *et seq.*; and

(z) *Wisconsin*: The aforementioned practices by defendants were and are in violation of Wisconsin's unfair competition statute, Wis. Stat. §100.20 *et seq.*

249. Plaintiffs and members of the Class have been injured by reason of defendants' violations alleged in this Count. Their injuries consist of: (a) being denied the opportunity to purchase lower-priced epinephrine auto-injector products sooner; and (b) paying higher prices for EpiPen products than they would have paid in the absence of defendants' conduct. These are the type of injuries these laws are designed to prevent, and flow from that which makes defendants' conduct unlawful.

250. Plaintiffs and the Class seek damages, multiple damages, treble damages, and other damages and relief, including disgorgement, as permitted by state law, for defendants' violations pursuant to these statutes.

COUNT V

Unjust Enrichment and Disgorgement of Profits Against All Defendants

251. Plaintiffs reallege and incorporate the preceding allegations of this Complaint with the same force and effect as if fully restated herein.

252. Defendants have benefited from the monopoly profits on EpiPen product sales, resulting from the unlawful and inequitable acts alleged in this Complaint.

253. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for EpiPen products by plaintiffs and members of the Class.

254. Plaintiffs and the Class have conferred upon defendants an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of plaintiffs and the Class.

255. It would be futile for plaintiffs and the Class to seek a remedy from any party with whom they had a privity of contract. Defendants have paid no consideration to anyone for any benefits received indirectly from plaintiffs and the Class. Similarly, it would be futile for plaintiffs and the Class to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which they indirectly purchased EpiPen products, as they are not liable and would not compensate plaintiffs for unlawful conduct caused by defendants. The economic benefit of overcharges and unlawful monopoly profits derived by defendants through charging supracompetitive and artificially inflated prices for EpiPen products are a direct and proximate result of defendants' unlawful practices.

256. The financial benefits derived by defendants rightfully belong to plaintiffs and the Class, as plaintiffs and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to the benefit of defendants.

257. It would be inequitable under the laws of all states and jurisdictions within the United States for defendants to be permitted to retain any of the overcharges for EpiPen products derived from defendants' unfair, deceptive, and unconscionable methods, acts and trade practices alleged in this Complaint.

258. Defendants should be compelled to disgorge in a common fund for the benefit of plaintiffs and the Class all unlawful or inequitable proceeds received by them. A constructive trust should be imposed upon all such unlawful or inequitable sums received by defendants traceable to plaintiffs and the Class.

259. Plaintiffs and the Class have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs request that the Court enter judgment on plaintiffs' behalf and on behalf of the Class herein, adjudging and decreeing that:

A. This action may proceed as a class action, with plaintiffs as the designated Class representatives and their counsel as Class Counsel;

B. Defendants have engaged in a combination and conspiracy in violation of §§1 and 2 of the Sherman Act, 15 U.S.C. §§1 and 2, and plaintiffs and the members of the Class have been injured in their business and property as a result of defendants' violation;

C. Plaintiffs and the members of the Class are entitled to recover damages sustained by them, as provided by the state antitrust laws listed in Count III and the consumer protection laws listed in Count IV, an injunction under federal antitrust laws, and that a joint and several judgment in favor of plaintiffs and the Class be entered against defendants in an amount to be trebled in accordance with such laws;

D. Ordering reimbursement, restitution and disgorgement from defendants of the benefits unjustly conferred on them by plaintiffs and the Class;

E. Defendants, their subsidiaries, affiliates, successors, transferees, assignees and the respective officers, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf be permanently enjoined and restrained from continuing and maintaining the combination, conspiracy or agreement alleged herein;

F. Plaintiffs and members of the Class be awarded pre-judgment and post-judgment interest, and that such interest be awarded at the highest legal rate from and after the date of service of the initial Complaint in this action;

G. Plaintiffs and members of the Class recover their costs of this suit, including reasonable attorneys' fees as provided by law; and

H. Plaintiffs and members of the Class receive such other or further relief as may be just and proper.

JURY DEMAND

Pursuant to Fed. R. Civ. P. 38, plaintiffs on behalf of themselves and the proposed Class demand a trial by jury on all issues so triable.

DATED: April 7, 2017

CARELLA, BRYNE, CECCHI, OLSTEIN, BRODY & ANGELLO, P.C.

By: */s/ James E. Cecchi*
James E. Cecchi
Michael A. Innes
5 Becker Farm Road
Roseland, NJ 07068
Telephone: 973/994-1700
973/994-1744 (fax)

Damien J. Marshall
Duane L. Loft
BOIES, SCHILLER & FLEXNER LLP
575 Lexington Avenue, 7th Floor
New York, NY 10022
Telephone: 212/446-2300
212/446-2350 (fax)

Paul J. Geller
Stuart A. Davidson
ROBBINS GELLER RUDMAN
& DOWD LLP
120 East Palmetto Park Road, Suite 500
Boca Raton, FL 33432
Telephone: 561/750-3000
561/750-3364 (fax)

Brian O. O'Mara
Arthur L. Shingler III
ROBBINS GELLER RUDMAN
& DOWD LLP
655 West Broadway, Suite 1900
San Diego, CA 92101-8498
Telephone: 619/231-1058
619/231-7423 (fax)

Brian D. Penny
GOLDMAN SCARLATO & PENNY, P.C.
161 Washington Street, Suite 1025
Conshohocken, PA 19428
Telephone: 484/342-0700
484/580-8747 (fax)

Attorneys for Plaintiffs